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CHARACTERISTICS OF DEPARTMENT OF DEFENSE MEDICAL MALPRACTICE CLAIMS: AN UPDATE

A Quality Management Tool for DoD(HA), the TRICARE Lead Agents and the MTF

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INTRODUCTION

Medical malpractice data collection and trend analysis has become standard practice for many large managed care organizations and insurers in the United States. The Department of Defense (DoD) and the Department of Veterans Affairs have established medical malpractice claim databases for the purposes of quality improvement and risk management. Insurers in the private sector, such as the St. Paul Fire and Marine Insurance Company and the Physician Insurers Association of America, a national organization of 47 physician-owned professional liability insurance companies, collect risk management data in similar fashion. Federal agencies that directly provide health care have an additional interest in collecting such data. Congress and the Government Accounting Office have repeatedly demonstrated a special interest in the medical liability experiences of those federal agencies.[1]

Medical malpractice data has also been used to support other quality management efforts. Liability data can highlight specific areas potentially needing focused study by other quality improvement programs, such as those for patient care assessment and external peer review. For example, some DoD studies undertaken by the Civilian External Peer Review Program were implemented in response to medical malpractice data. In the Department of Veterans Affairs, a number of treatment facilities use malpractice data to focus other quality management programs. Finally, malpractice case summaries can serve to educate healthcare providers about past mistakes and those areas of clinical practice with greater exposure to claims. Medical malpractice analysis, therefore, will likely continue to be an important component of the health care quality management programs of DoD and the Department of Veterans Affairs for some time.

This article is an update regarding the DoD medical malpractice database maintained by the Office of the Assistant Secretary of Defense (Health Affairs) with assistance of the Department of Legal Medicine, Armed Forces Institute of Pathology. Since 1991, the Department of Legal Medicine has annually reported summaries from the database to the DoD (Health Affairs) Risk Management Subcommittee and to the Joint Service Quality Management Committee. Currently, the database contains information abstracted from medical malpractice claims involving DoD health care facilities, resolved between 1988 and 1995. Claims are resolved or "closed" when final legal action has been taken. An initial report, describing the data collection process and entries from the first 1,544 closed malpractice claims submitted to the project, was presented in *Legal Medicine Open File* in 1992.[2] The database, alternatively known as the "abstracts of closed medical malpractice claims database" or "Tort-2", contains 63 fields or data elements. Because of the difficulty involved in obtaining a high level of detailed medical and legal information from incidents occurring several years earlier, data abstracted from closed malpractice claims are at times incompletely reported. This results in different totals for specific data elements as well as reduces the total number of complete reports. Nevertheless, this database contains a significant portion of complete closed DoD malpractice claims. Incomplete reporting has been reduced by developing an improved data collection form, DD Form 2526, and a procedure manual, as well as conducting periodic meetings of appropriate personnel assigned to this function from the three Offices of the Surgeons General.

HISTORICAL MALPRACTICE DATA

Since the mid-1980's, the number of medical malpractice claims filed against the DoD has usually been in the range of 700–900 claims per year (Table 1). For 1993 and 1994, the average number of claims filed was 1,035. This may solely reflect an actual increase and represent the beginning of an elevation of malpractice claims activity for DoD. However, this increase may also reflect the increasing trend for a single malpractice case to generate numerous claims from relatives of the patient-claimant.

TRENDS IN DOD MALPRACTICE CLAIMS

YEAR	NUMBER FILED	TOTAL DOD MD/DO YEAR END STRENGTH	RATE/ 100 MDs/ DOs
1986	895	13269	6.7
1987	876	13191	6.6
1988	995	13226	7.5
1989	872	13442	6.5
1990	685	13815	5.0
1991	653	14225	4.6
1992	776	14276	5.4
1993	996	14076	7.0
1994	1073	13709	7.8

TABLE 1

Since 1986, the rate of claims per 100 physicians in DoD has been in the range of 4.6–8. This is compared to data from the St. Paul Fire and Marine Insurance Company in Figure 1. Their experience is approximately 13–15 claims per 100 insured physicians annually.[3] The information is reported as claims filed per 100 physician providers, because that is a common format for reporting the frequency of malpractice suits by private insurers. Exact comparison with private sector claims experience is difficult for three reasons. First, some adjustment downward of the DoD rate might be justified given that physicians are the specified responsible parties in only 85–90 percent of DoD malpractice claims. Second, the Feres Doctrine, which precludes active duty service members from filing this type of claim, necessarily affects the rate reported for DoD. Were active duty members permitted to file calms, the DoD rate would increase. Third, multiple federal claims can result from a single incident. If only cases are reported, as common in the private sector, the DoD rate would decrease.

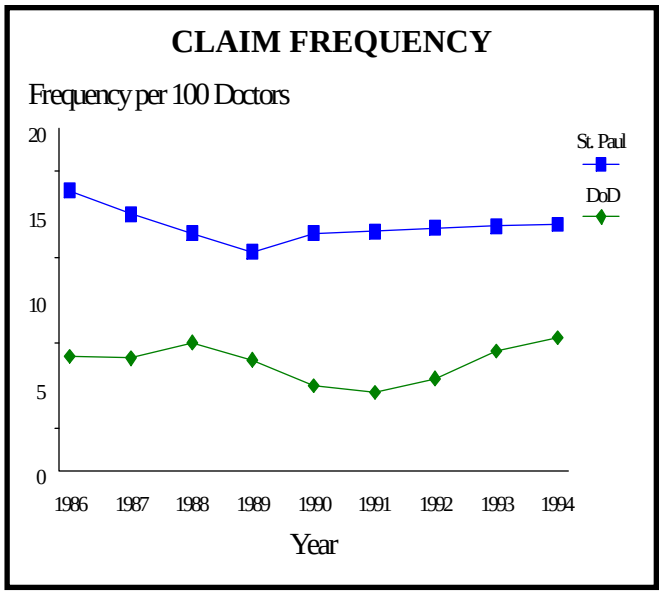

FIGURE 1

PATIENT CHARACTERISTICS

Nearly one-fourth of patients involved in DoD malpractice claims are less than two years of age. Approximately two-thirds of claims involve patients over the age of 19. St. Paul recently reported the age breakdown of patients for their paid cases.[4] An age comparison of DoD and St. Paul paid claims is depicted in Figure 2.

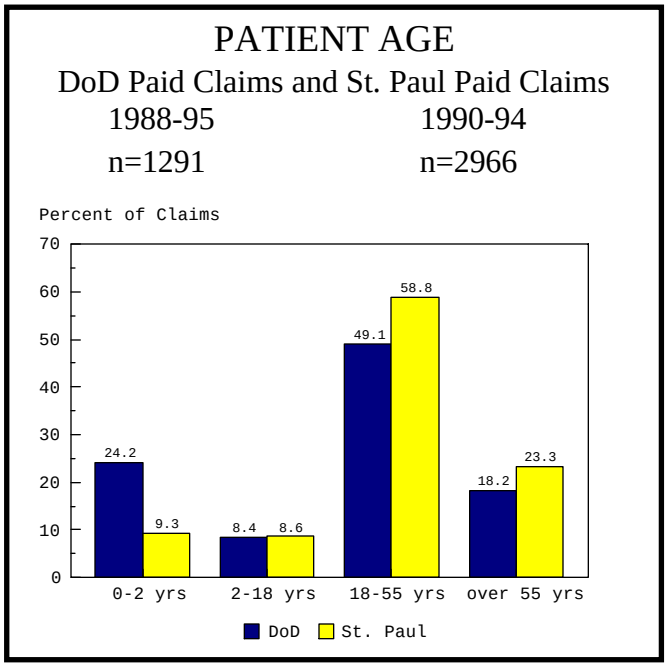

FIGURE 2

Fifty-four percent of patients filing DoD medical malpractice claims were dependents of active duty service members, and approximately 30 percent were retirees or their dependents.

With regard to the severity of injury for patients involved in DoD claims, nearly 23 percent died, 16 percent experienced no injury, and the remainder had some degree of injury.

CLAIM CHARACTERISTICS

Figure 3 illustrates the legal outcome of 2,910 malpractice claims for which such data were available. Approximately one-quarter of the claims were settled administratively by the respective military service. Over one-third, 34.3 percent, were denied as nonmeritorious. Other bases, such as the statute of limitations and the Feres Doctrine, supported the administrative denial of another 15 percent. Twenty-five percent of claims proceeded to litigation. They were then managed by the Department of Justice, who settled more than 14 percent without a trial. Only ten percent of claims were formally litigated in a federal court. The government successfully defended approximately 60 percent of those cases.

Concerning the nature of the primary malpractice allegation, various codes for act or omission were created for Tort-2, and 3,077 entries are reported at

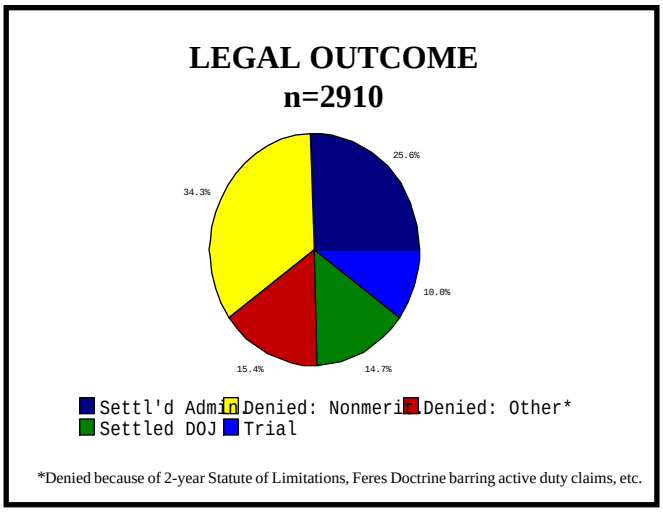

FIGURE 3

Figure 4. Forty percent of those claims, for which such data were available, involved allegations related to diagnoses. These included such acts or omissions as failure to diagnose a disease or condition, misdiagnosis of an existing condition, improper performance of a diagnostic test, a delay in diagnosis, and failure to obtain informed consent. Twenty-one percent of the primary allegations were related to surgery. These included allegations of retained foreign bodies, operations on the wrong body part, improper performance of surgery, unnecessary surgery, delay in surgery, improper management of a surgical patient, and failure to obtain informed consent for surgery.

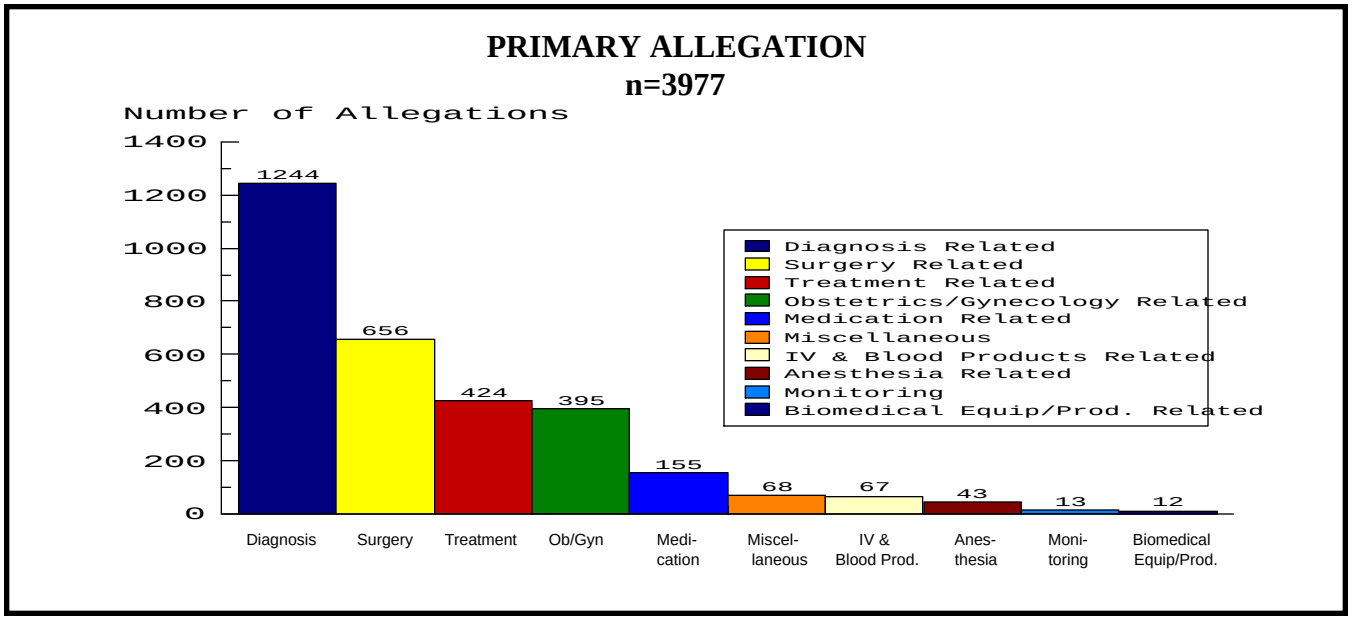

FIGURE 4

Fourteen percent of the claims were related to treatment. They included such allegations as failure to treat, improper performance of a treatment or procedure, improper management of a course of treatment, premature end of treatment, and failure to seek consultation. Thirteen percent of the sample claims were related to obstetrics. These included failure to adequately manage pregnancy, improperly performed vaginal delivery, improperly performed cesarean section, a negligent delaying delivery, improperly managed labor, and failure to identify and treat fetal distress.

Approximately five percent of the claims were related to medication. These included failing to order appropriate medication, ordering the wrong medication, ordering the wrong dosage of the correct medication, improperly monitoring medication, failing to obtain informed consent for medication, administering the wrong medication, administering the wrong dosage, and using improper technique in administering medication. Approximately two percent of the claims were related to intravenous procedures and blood products. These included failure to insure the solution to be contamination-free and utilization of an improper type of infusion. A small percentage (1.4 percent of the claims included acts or omissions related to anesthesiology. These included failure to complete an adequate patient assessment, failure to monitor a patient, improper choice of an anesthetic agent or equipment, negligent use of equipment, improper intubation, and improper positioning of a patient.

Miscellaneous allegations, comprising of 2.2 percent of the total, included inappropriate or unprofessional behavior of a clinician, breach of confidentiality or privacy, and failure to follow an institutional policy or procedure. Approximately 0.5 percent of the claims related to patient monitoring. These included such allegations as failure to monitor, failure to respond to a patient, and failure to report on a patient's condition. Another 0.5 percent of the claims were related to biomedical equipment/products. These included such allegations as failure to inspect or monitor the equipment, improper maintenance, improper use, and malfunctions/failures.

In its 1994 annual report, the St. Paul Fire and Marine Insurance Company described the claims experience of the Company using major allegation groups.[5] Figure 5 depicts a comparison of malpractice claim categories between DoD and St. Paul. The relative rates for DoD are lower for surgical and treatment related claims, while higher for claims related to diagnoses.

As stated above, in the DoD database, approximately 5 percent of allegations were related to medication. This area of practice has recently been studied in the private sector. The Physician Insurers Association of America, in 1993, completed a medication error study that referenced closed claims from twenty-four member companies.[6] Of 90,166 total claims analyzed, 6,646, or 13.6 percent, involved medication errors. The four most frequent medication errors reported were incorrect or inappropriate dosage, medication inappropriate for condition, failure to monitor drug side effects, and communication failure between physician and patient. In DoD, the most frequent medication errors were administering the wrong medication and ordering the wrong medication.

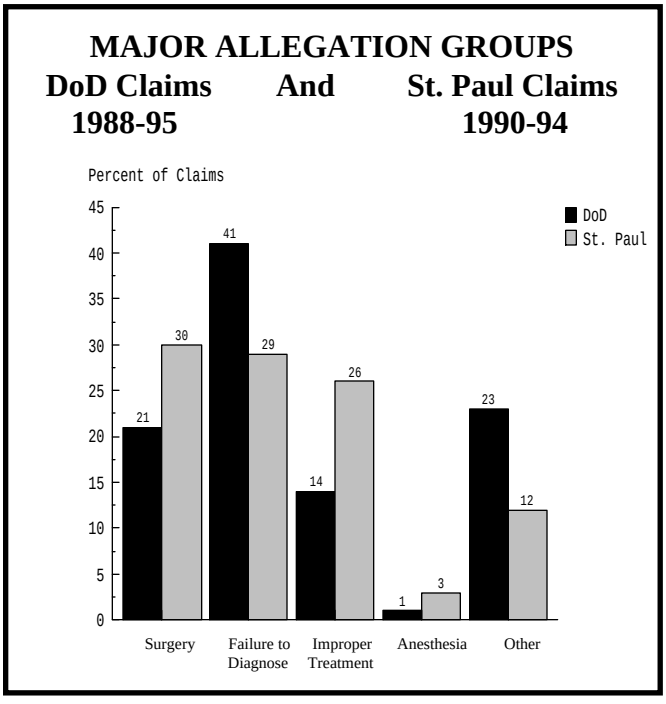

FIGURE 5

PROVIDER AND FACILITY CHARACTERISTICS

Figure 6 depicts the attributions of fault for 2,777 DoD claims for which data were available. In 83.2 percent of cases, the attribution of fault is to a physician. Personnel

other than physicians were involved in 8.5 percent of the claims. Facility and/or equipment problems were involved in 4.3 percent of the claims. System or management failures, as the sole source of responsibility, occurred in 2.7 and 1.3 percent of the claims, respectively.

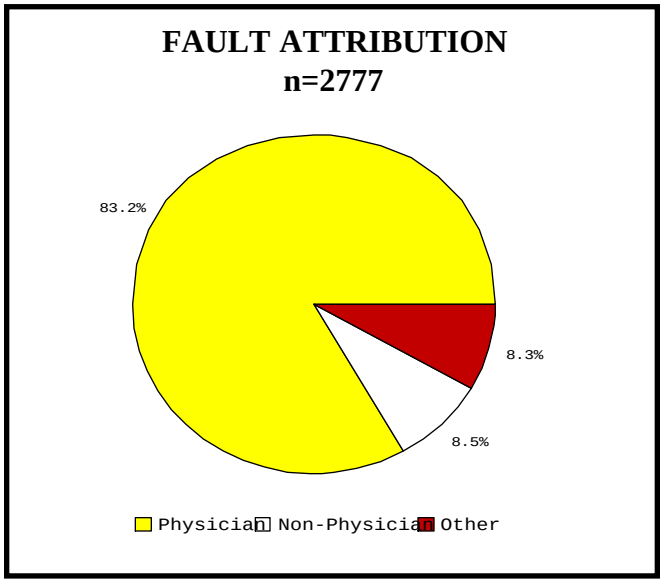

FIGURE 6

Within a treatment facility, the locale for the alleged malpractice was an inpatient setting for 64.8 percent of the claims and an outpatient setting for 28.4 percent. The remainder of allegations were distributed among dental and ancillary services. The distribution of clinical services by specialty for 1,700 reported DoD claims, for which data are available, is listed at Tables 2a and 2b. The most frequent inpatient services involving malpractice claims were obstetrics/gynecology, surgery and medicine. The most frequent outpatient services involving malpractice claims were emergency care, medicine and primary medical care.

In 1994, St. Paul reported that 59.4 percent of its claims (4,166 of 7,010) arose in a hospital setting while 40.6 percent (2,844 claims) occurred outside the hospital. That insurer considers the latter figure a reflection of the steady growth in outpatient malpractice claims for recent years as outpatient medical care has become increasingly more common.[7]

The primary provider was a physician in 90 percent of the DoD claims. In only 2.2 percent of the claims, the primary provider was a physician assistant, and dentists were involved in 2.0 percent of the claims. Nurses were involved in 4 percent of the claims, with the following distribution: registered nurses, 1.3 percent; nurse practitioners, 1 percent; nurse anesthetists, 0.9 percent; nurse midwifes, 0.8 percent.

Table 3 identifies the ten provider specialties most frequently involved in the 1,343 DoD claims for which data are available. Obstetrics/gynecology (22.5) and surgery (18.5) are the most frequently represented specialties. In the private sector, a similar level of heightened claims exposure prevails for providers of obstetrics and gynecology. According to a 1994

INPATIENT CLINICAL SERVICES
n=1182

	Number of Claims	Percent
Obstetrics/Gynecology	435	36.8
Surgery	367	31.1
Medicine	129	10.9
Orthopedic Surgery	102	8.6
Pediatrics	94	8.0
Family Practice	35	3.0
Psychiatry	20	1.7

TABLE 2a

OUTPATIENT CLINICAL SERVICES
n=518

	Number of Claims	Percent
Emergency Medicine	189	36.5
Medicine	96	18.5
Primary Medicine	63	12.2
Obstetrics/Gynecology	55	10.6
Surgery	39	7.5
Pediatrics	27	5.2
Family Practice	24	4.6
Orthopedic Surgery	12	2.3
Flight Medicine	8	1.5
Psychiatry	5	1.0

TABLE 2b

TEN MOST FREQUENTLY NAMED SPECIALTIES n=1343

	Number of Claims	Percent
Obstetrics/Gynecology	302	22.5
Surgery	248	18.5
Internal Medicine	130	9.7
Family Practice	123	9.2
Pediatrics	85	6.3
Orthopedic Surgery	79	5.9
General Medical Officer	75	5.6
Radiology	41	3.1
In Training	38	2.8
Emergency Medicine	35	2.6

TABLE 3

DIAGNOSTIC GROUPS n=3026

Pregnancy/Childbirth/Puerperium	520
Neoplasms	426
Circulatory System	308
Injury & Poisoning	281
Musculoskeletal & Connective Tissue	256
Genitourinary System	246
Digestive System	242
Nervous System & Sense Organs	176
Symptoms/Signs/Ill-Defined Conditions	98
Respiratory System	89
Perinatal Period	88
Infectious & Parasitic Diseases	85
Endo/Nutritional/Metabolic/Immunity	64
Mental Disorders	45
Skin & Subcutaneous Tissue	41
Congenital Anomalies	35
Blood & Blood Forming Organs	26

TABLE 4

survey of 4,100 members of the American College of Obstetrics and Gynecology, 79.4 percent had been sued at least once in their careers.[8]

STANDARD OF CARE AND DIAGNOSES

Within DoD, determinations regarding the standard of care are formulated at the involved medical treatment facility and conclusively reviewed within the Office of the Surgeons General in the respective services. These determinations were available for 2,983 claims in Tort-2. The standard of care was considered met in 65.4 percent of claims and not met in 28.0 percent of claims. No determination was rendered in the remainder because of inadequate information available to reviewers.

Table 4 depicts the distribution of 3,026 DoD claims, for which data were available, within the 17 diagnostic groups of ICD9-CM coding system. Diagnoses of pregnancy, childbirth, and the puerperium was the most frequently represented diagnostic group (17.2 percent of claims). Approximately 14 percent of claims involved in neoplasms, and 10.2 percent of claims involved the circulatory system.

The most frequent specific diagnoses listed in the database are cancer of the breast, ischemic heart disease, fetal/placental problems, cancer of the lung, female genital pain, acute appendicitis and ectopic pregnancy. The most frequently specified surgical procedures are cesarean section, vaginal delivery, abdominal laparotomy, breast surgery, coronary artery bypass surgery, on the Fallopian tubes and spinal cord surgery.

PAYMENT INFORMATION

Table 5 reports the amounts of money paid for the resolution of 1,281 DoD malpractice claims from 1988 through 1995. A total of $309,158,644 was paid for those claims entered into the database. Payments were made in approximately 40 percent of reported claims. Only 5 percent of claims were closed with payment that exceeded one million dollars, but they accounted for nearly half (47.6 percent) of the total amount paid. On the other hand, only 4 percent of the total was paid to resolve nearly half the claims, those with payments of $50,000 or under.

A RISK MANAGEMENT TOOL

Medical malpractice data collection can be an important quality management tool. This is especially true

AMOUNTS PAID
n=1281

AMOUNT ($)	PERCENT OF CLAIMS	SUM ($)	PERCENT OF TOTAL AMOUNT PAID
0 - 10,000	18.0	1,309,098	0.4
10,001 - 25,000	20.8	5,529,367	1.8
25,001 - 50,000	10.8	5,603,317	1.8
50,001 - 100,000	13.8	14,108,396	4.6
100,001 - 200,000	14.7	30,167,046	9.8
200,001 - 500,000	11.2	49,176,319	15.9
500,001 - 1,000,000	5.7	55,960,184	18.1
1,000,001 - 12,000,000	5.0	147,304,917	47.6
TOTAL AMOUNT PAID		309,158,644	

TABLE 5

when that information is scrutinized to highlight clinical areas of noteworthy risks that, in turn, may be subjected to other forms of more thorough quality analysis. For those purposes, DoD has directed the contractor for the Civilian External Peer Review Program, on numerous occasions, to review certain areas of medical practice rendered in military facilities.

Further, for some time, malpractice occurring in federal medical facilities has been a topic of recurring interest on the part of both Congress and the public.

The Tort-2 database represents a constant effort on the part of DoD to analyze malpractice information critically to employ it properly within the entire spectrum of DoD risk management activities. There are certain diagnoses, procedures, specialties, and medical services that appear relatively frequently among all claims entered into the database. These may well be candidates for worthwhile focused study. National professional societies, such as the American Society of Anesthesiology, have expressed interest in combining data entries from DoD cases with that derived from private sector cases for specialty risk management assessment and education. This type of professional dissemination from and to skilled health care providers, within both the federal and civilian sectors, should substantially contribute to both the maintenance and improvement of quality standards.

With the development of the 12 TRICARE regions, Tort-2 reporting will be modified. Region specific reports will be forwarded to each of the 12 regions and to TRICARE Europe. This data should constitute another useful tool for lead agents to assess the quality of care rendered in their region. Data collection from the managed care support contractors will also be explored in an attempt to monitor the quality of care delivered to DoD beneficiaries by network providers.

To further augment the comparisons of DoD experience with those of civilian health care providers, a memorandum of agreement has been entered with the Department of Health and Human Services for the purpose of studying malpractice payments registered in the National Practitioner Data Bank. Database entry comparisons for such fields as provider licensure and act or omission codes will substantially contribute to these efforts.

In addition, St. Paul is establishing a more comprehensive malpractice data collection effort, that will examine, in addition to information already reported, diagnostic groups.[9] This should enhance DoD's ability to formulate comparisons with their data.

The Department of Legal Medicine will continue to analyze the malpractice experience of the federal and private sectors to improve the utility of the Department of Defense database as an instrument for quality improvement.

REFERENCES

1. United States General Accounting Office. DoD Health Care: Better Use of Malpractice Data Could Help Improve the Quality of Health Care. Washington, D.C.: United States General Accounting Office; June 1987.

2. Granville R. et al. Some characteristics of Department of Defense malpractice claims: An initial report. Legal Medicine Open File. 1992; 92:1-10.

3. Medical Services Division, St. Paul Fire and Marine Insurance Company. Physicians and Surgeons Update: 1995 Midyear Report from the St. Paul Fire and Marine Insurance Company. St. Paul, MN: The St. Paul Companies, Inc.; 1995:1.

4. Medical Services Division, St. Paul Fire and Marine Insurance Company. Physicians and Surgeons Update: 1995 Midyear Report from the St. Paul Fire and Marine Insurance Company. St. Paul, MN: The St. Paul Companies, Inc.; 1995:7.

5. Medical Services Division, St. Paul Fire and Marine Insurance Company. Physicians and Surgeons Update: Year-End Report from the St. Paul Fire and Marine Insurance Company. St. Paul, MN: The St. Paul Companies, Inc.; 1994:4.

6. Physician Insurers Association of America. Medication Error Study. Washington, D.C.: Physician Insurers Association of America; June 1993.

7. Medical Services Division, St. Paul Fire and Marine Insurance Company. Physicians and Surgeons Update: Year-End Report from the St. Paul Fire and Marine Insurance Company. St. Paul, MN: The St. Paul Companies, Inc.; 1995:4-5.

8. Clements B. Don't Get Sued: Dangerous Deliveries. American Medical News. 1994; 37, 29:15-17.

9. The St. Paul Medical Services Hospital Update. Accusystem: New Hospital Insurance Tool. St. Paul, MN: The St. Paul Companies, Inc., 1994:1.

MANAGED CARE LIABILITY

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"Managed care" encompasses various mechanisms by which large systems administer the financing and delivery of health care. One such mechanism is the development of criteria to control the utilization of clinical services, such as diagnostic tests and procedures. Another is the imposition of restrictions on specialty referrals. The systems employing the mechanisms have been designated, among other things, health maintenance organizations (HMOs) and preferred provider organizations (PPOs).

Whatever the nomenclature, however, managed care is revamping many aspects of the traditional physician-patient relationship. Independent medical practitioners who once performed on a fee-for-service basis and managed their own practices as small businesses are being replaced by physicians operating within larger systems that control reimbursement. While practitioners previously made essential independent medical decisions, the current momentum is toward a system in which these decisions are subject to insurer review, with a goal of cost containment.[1] Civilian practitioners, particularly those in practice for 20 years or more, have witnessed a gradual evolution in health care delivery. Military physicians are now, or will soon be, experiencing similar changes under the Department of Defense Tricare Health Delivery System.

CHANGING THE HEALTH CARE LANDSCAPE

Civilian physician referral patterns have already been altered by managed care reimbursement arrangements. Whereas primary care physicians would previously refer fractures to a trusted local orthopedic surgeon, insurer restrictions often exclude such familiar specialists and instead mandate referrals to "participating" orthopedic surgeons with whom the primary care physician may have had little or no prior contact.

Diagnostic testing has also been affected. Not only do certain objective criteria often have to be met before reimbursement is approved, but the site of performance for approved tests may also be restricted to designated locations or laboratories. If radiographs are performed on site in a large outpatient setting, existing practice procedures which provide for review of all studies by a radiologist may be abandoned as a cost savings mechanism. Rather than the blanket review of all films by radiologists, primary care physicians may be responsible for a definitive diagnostic interpretation of more common studies with subsequent readings by radiologists reserved for highly specialized examinations.

Inpatient practices have also undergone revision, modifying further the parameters of the traditional physician-patient relationship. Admission for many diagnoses may only be approved if certain criteria regarding patients' signs and symptoms have been met. Other diagnoses limit the duration of hospitalization for which the provider will be reimbursed.

PHYSICIAN LIABILITY

There are changes in physician liability which have accompanied the managed care revolution. Preferred provider organizations, health maintenance organizations, and similar systems have altered the application of traditional liability theories. Some of these changes have already spawned litigation, and some have the potential to alter the legal landscape.

Many experts view the gatekeeper role as one that increases the liability exposure of primary care providers.[2] Few claims currently attempt to impose liability using the gatekeeper concept. The nation's largest medical liability carrier, the St. Paul Fire and Marine Insurance Company, has noted, however, an increase in "failure to diagnose" claims.[3] With the emphasis on reducing specialty referrals and limiting sophisticated diagnostic studies, one wonders if primary care providers' gatekeeping role will increase their liability for failure to diagnose serious conditions. Claims arising from care rendered in physicians' offices have also seen a sharp increase from 32.6 percent of reported claims in 1988 to more than 45 percent in 1992.[4] Again, this increase in office-based claims may be coupled with the current trend away from hospitalization and aggressive specialty evaluations and could represent a shifting of liability risks to the office-based generalist.

Managed care liability concerns, however, are not limited to the gatekeeper concept. Insurer authorization of hospital stays has provoked much discussion, and at least one leading case, *Wickline v. State of California*,[5] illustrates the potential legal risks of cost-containment systems. In that case, Lois Wickline experienced problems associated with her back and legs. Her family practitioner admitted her to the hospital for evaluation and consulted a specialist in peripheral vascular surgery. Following examination, the surgeon diagnosed her as suffering from arteriosclerosis obliterans with occlusion of the abdominal aorta just above the division of the iliac arteries.

Surgery was recommended, and because of the advanced arteriosclerosis, removal of a portion of the vessel and insertion of a synthetic graft was contemplated. The patient agreed to the surgery and was discharged home, pending authorization of the procedure from Medi-Cal, California's medical assistant program. The patient's family practitioner submitted a treatment authorization request and Medi-Cal approved the prospective surgery with 10 days of accompanying hospitalization.

The patient was admitted, and surgery was performed. The peripheral vascular surgeon was notified later on the same day of the surgery that Ms. Wickline was experiencing circulatory problems in her right leg. He suspected the development of a clot in the graft, and returned her to the operating room, where he reopened her right groin incision, identified and removed a clot, and resewed the graft. Her postoperative course was characterized by pain, spasm of lower extremity vessels, and hallucinations. Five days following the initial surgeries, Ms. Wickline was again returned to the operating room where a lumbar sympathectomy was performed to stop vasospasms and prevent clotting.

Her stormy postoperative course convinced the surgeon that an extension of her ten-day hospitalization was medically necessary. The main reason for extending hospitalization, in his mind, was to continue close observation, so that he could immediately address any additional postoperative complications that threatened limb preservation. The dangers of clotting and infection were viewed as significant enough to require continued inpatient management.

Since Ms. Wickline was a patient in California's medical assistant program, a request to Medi-Cal was prepared by the hospital's representative, in this case, a registered nurse, based upon information furnished by the surgeon. An additional eight days of hospitalization were requested. At Medi-Cal, the request was initially reviewed by their representative, another registered nurse, who felt that she could not approve the eight-day extension. She telephoned the Medi-Cal consultant, a board certified general surgeon, and presented the clinical circumstances triggering the eight-day extension request. A four-day extension, only half of that requested, was then approved by Medi-Cal. The Medi-Cal consultant later testified that, on the information provided to him, it appeared that Ms. Wickline was not seriously ill and was progressing satisfactorily. The opinion of a peripheral vascular surgeon, however, was not solicited.

While the surgeon caring for Ms. Wickline disagreed with Medi-Cal's decision, he later testified that he thought they had the power to limit the duration of hospitalization. Accordingly, he discharged the patient four days earlier than he had planned, after explaining to her and her husband how the lower limbs should be cared for at home.

Soon after she returned home, Ms. Wickline experienced pain and a loss of color in the right leg. With the passage of several more days, the pain intensified and the leg appeared whitish. The patient initially did not contact her physician because she thought these changes were part of the normal recovery process. When her husband did call the physician, additional pain medication was prescribed. Finally, the pain became excruciating, and her husband again telephoned her physician, who recommended that she return to the hospital.

Nine days after her discharge from the hospital, she was readmitted. On examination, she was found to have a secondary infection of her right groin incision, a mottled right foot and a cool right leg. Physicians concluded that clotting had obstructed circulation to the leg. Because of the infection at the graft site, it was deemed inadvisable to surgically remove the clot because of the risk of septicemia. Instead, a regimen of anticoagulants, antibiotics, whirlpool baths, and bed rest was prescribed. These measures eventually proved unsuccessful, and ten days after hospital readmission, the patient's right leg was amputated.

The patient brought suit against Medi-Cal, arguing that their refusal to grant a full eight-day extension represented

negligence in the form of a premature discharge and caused the loss of the limb. At trial, the peripheral vascular surgeon who initially operated on Ms. Wickline testified that, had the requested eight-day extension been granted by Medi-Cal, he would have been able to observe a color change and remove the clot from her graft, thereby saving the leg. Other experts disagreed, however, and stated that failure to continue hospitalization did not contribute to the loss of the limb.

A jury verdict for the plaintiff was returned. The State of California appealed, maintaining that the decision to discharge was made by a physician, not by Medi-Cal, and that if anyone is to blame for a premature hospital discharge, it is the attending physician. After hearing arguments on both sides, the court of appeals reversed the previous judgment for the plaintiff, holding that the State of California was not liable. In its opinion, the court pointed out that "Medi-Cal did not override the medical judgment of Wickline's treating physicians at the time of discharge."[6] Medi-Cal was merely implementing cost containment measures in a system of indigent health care but the decision to discharge was made by professionals. Pointedly, the court noted that the attending surgeon neither questioned nor appealed the limitation of the authorized hospital stay by Medi-Cal. Thus, Medi-Cal and the State of California ultimately escaped liability.

Legal commentators have noted that, although none of Ms. Wickline's physicians were named as defendants in this case, the appellate decision is significant for what it says about them and about physicians whose decisions conflict with managed care systems in the future.[7] In the court's view, physicians must continue to act reasonably and operate in the patient's best interests, regardless of economic pressures or cost containment system regulations. Moreover, the opinion strongly suggests that if medical necessity dictates a certain course of action, and the patient's needs conflict with a utilization review decision, the physician is obligated to appeal such an administrative decision. In the court's view, physicians will still be held accountable for patient management decisions, despite contrary managed care policies.

A somewhat similar problem was presented in the more recent case of *Wilson v. Blue Cross of Southern California*.[8] There, the patient's two-month weight loss of 20 pounds and a diagnosis of drug dependency with major depression led to a psychiatric admission. The attending physician's treatment plan called for inpatient hospitalization for a period of three to four weeks. The patient's insurer, however, ruled that continued hospitalization beyond ten days was not medically necessary, and that any financial liability for future days of hospitalization would be borne by the patient himself. The physician did not appeal the insurer's decision but discharged the patient, who committed suicide shortly thereafter.

The patient's mother, as administrator of his estate, brought suit against the medical insurer and the utilization review firm that had refused to fund his continued hospitalization. She alleged that their action represented negligence and a tortious breach of contract which resulted in her son's death. Interestingly, as in the *Wickline* case, the patient's physician was not a named defendant.

At trial, a summary judgment was entered for the defendants, based upon the prior *Wickline* decision which was construed to hold that only physicians are legally accountable for discharge decisions. Upon appeal, the trial court's decision for the defendants was reversed, and the appellate court made clear that the lower court's decision was based on an overly broad interpretation of *Wickline*. In fact, the opinion stressed that insurers were not immune from such suits and that both physicians and insurers could be held liable, under the proper circumstances, for a negligent, premature hospital discharge. Perhaps most significantly, the opinion noted that physicians have a responsibility to appeal patient benefit denials, if such decisions conflict with medical necessity and the patient's best interests. The case was remanded for trial, but the parties subsequently entered into a settlement.

Both the *Wickline* and *Wilson* decisions illustrate the changing landscape of medicine in a managed care environment. Medical decisionmaking, formerly the sole province of physicians, now is shared with health insurers and the utilization review entities they may employ to control costs.[9] The cases also stand for a potential expansion of liability to these other medical decisionmakers. Future cases will more clearly define how these newer liability targets fit into the traditional malpractice scenario. For physicians, it is clear that sound clinical practice and aggressive advocacy of the patient's interest, when medical necessity dictates, will continue to be the best formula for avoiding liability.

A REFERRAL LIABILITY: A POTENTIAL CAUSE OF ACTION

Ultimately, the most dangerous liability risk in managed care systems may involve referrals. Commentators have noted the propensity of malpractice attorneys to seek "new theories of liability,"[10] and referral by a primary care provider to a participating specialist with whom he is unfamiliar may provide that opportunity.

Since speciality referral within managed care systems is often limited to a participating provider list, there may be instances where the referring physician is totally unfamiliar with the specialist. For instance, if a patient with a breast mass is referred to a general surgeon who practices at a distant hospital, the referring physician may have no personal knowledge of the surgeon's competence regarding breast disease. If this surgeon's failure to biopsy or some other patient management decision is alleged to be negligent, a companion claim for negligent referral could conceivably be lodged against the referring physician. Evidence that the surgeon lacked board certification, previously mismanaged other breast mass patients at another hospital, or lacked competence in breast disease would only complicate the primary care provider's defense that he made a proper referral to a competent specialist.

Some have even suggested that referring physicians will face such great difficulty in ensuring referral to competent specialist within large, restrictive managed care systems that they should be insulated from liability through case law or state or federal legislation.[11] Without such legal protection, however, primary care physicians should take reasonable steps to avoid such liability through prudent inquiries. Development of new professional relationships with specialists, direct communication with those specialists and close patient follow-up remain valuable tools in ensuring the reasonableness of the referral.

The growth of managed care will continue to present both medical and legal challenges to practitioners. As time passes, case law will better define the legal responsibilities of all managed care participants, to include physicians, insurers, and utilization review companies. For now, there is no substitute for provider awareness that, despite practice changes, their primary legal and professional responsibilities remains with the patient, not the managed care organization.

REFERENCES

1. Hall MA. Managed competition and integrated health care delivery systems. Wake Forest Law Review. 1994;29:1,4-5.
2. Larkin H. "Lurking Liabilities," American Medical News. June 26, 1995, p.9.
3. Medical Services Division, St. Paul Fire and Marine Insurance Company. Physicians and Surgeons Update: Year-End Report from the St. Paul Fire and Marine Insurance Company. St. Paul, MN: The St. Paul Companies, Inc.;1994:1.
4. Id.
5. 228 Cal. Rptr. 661 (1986).
6. Id at 671.
7. Chittenden WA. Malpractice liability and managed health care: History and prognosis. Tort Insurance Law Journal. 1991;26:451.
8. 271 Cal. Rptr. 876 (1990).
9. Frankel JJ. Medical malpractice law and health care cost containment: Lessons for reformers from the clash of cultures. Yale Law Journal. 1994;103:1297.
10. Azzara AJ. Managed care referrals and malpractice law: Are you at risk? Family Practice Management. 1995;32:36.
11. Id.

BREAST CANCER MALPRACTICE CLAIMS
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Breast cancer, a disease now estimated to afflict 12 percent of women in this country, is a major public health issue for the United States.[1] Approximately 200,000 cases of breast cancer are newly diagnosed every year, and the disease annually causes the deaths of nearly 50,000 patients.[2]

Beyond the stark reality of epidemiologic data , this illness exacts a significant emotional toll. The threat of its potential appearance, the burden of its presence when diagnosed, and the consequences of its treatment pose a special if not unique invasion of bodily integrity and self-image for those afflicted.

Standard medical practice in the evaluation and treatment of breast cancer patients encompasses a broad and challenging level of professional skill, knowledge, care, and diligence.

A FEDERAL CASES

The patient, a 37-year-old dependent wife of an active duty military member, underwent a normal breast exam by her gynecologist in April 1985. She reported to the same provider a two-month history of fullness and tenderness in her right breast in March 1986, and he referred her to the general surgery clinic with a provisional diagnosis of fibrocystic disease, right greater than left.

The surgical consultation was chiefly recorded by a rotating medical student who evaluated the patient in April 1986 with an attending staff member. A negative family history for breast cancer was noted, and the patient had never undergone mammography. The breasts were described as small and symmetrical. There was a diffuse thickening of breast tissue on the right side throughout the medial inferior quadrant. The clinical impression was fibrocystic disease, and reevaluation at four weeks was ordered.

A general surgery house officer, with the same staff member attending as in April, provided reevaluation in May 1986. Firm, diffuse breast tissue, with small cysts, was again detected throughout the inferior medial quadrant of the right breast. The clinical impression remained fibrocystic disease. The patient was advised to conduct self-examinations monthly and to return to clinic at six months. The medical record included a specific notation that mammography was not indicated.

Another attending general surgeon evaluated the patient in March 1987. He detected the same area of diffuse right breast tissue thickness at the inferior medial quadrant. He considered these findings to likely represent fibrocystic disease, but advised the patient a biopsy was necessary and ordered mammography.

The mammogram revealed multiple suspicious microcalcifications, without evidence of a distinct mass. A subsequent breast biopsy revealed intraductal and infiltrative cancer. At the time of mastectomy in March 1987, one of 17 axillary nodes was positive for disease.

A federal malpractice claim was filed in March 1988. Metastatic disease was diagnosed in August 1990, and multiple organ system involvement was detected in April 1991. The patient's husband retired in June 1991 to assume the primary responsibility for the care of three dependent children.

The malpractice claim was investigated initially at the local command, where it was concluded that the care rendered at the time of the 1986 evaluations was incomplete. The full investigation of this case revealed that the patient had been substantially reassured at the time of her 1986 assessments and, when seeking reevaluation later, she was unable to obtain a necessary appointment for some time. Ultimately, opinions were secured with specialists from general surgery, oncology, pathology and radiology. They uniformly agreed that the diagnosis of breast cancer in this case was negligently delayed and that further studies should have been pursued in 1986 when the disease could have been diagnosed and treated.

This case was settled administratively, with a negotiated award and without litigation.

THE BREADTH OF PRECEDENT

In 1794, a Connecticut court issued the first written appellate opinion in the United States regarding medical malpractice. The case involved surgical care and the near immediate death of a woman who suffered a "scorfulous" breast lesion.[3]

In 1995, medical malpractice cases involving the diagnosis and treatment of breast cancer have become the most common form of liability claim filed against physicians in the United States. Specialists defending themselves in those cases include, among others, representatives from family practice, obstetrics-gynecology, internal medicine, general surgery, oncology, radiology, radiation oncology, and pathology.

The amount of money paid by medical liability insurance companies as indemnification for such cases makes them, by disease category, the most frequent cause for paid malpractice claims and a leader in the total amount of indemnification.

This publication and others similar, along with the traditional medical literature, have previously addressed this form of malpractice claim.[4] The frequency of those claims, their severity, and the experience of patients when serious errors arise in the diagnosis or treatment of breast cancer would appear to justify that level of attention.

THE PROFESSIONAL LITERATURE

Haagensen, in 1971, noted in his clinical series of 1,433 patients who had discovered their own breast cancers that 19 percent (270 cases) were initially misdiagnosed by physicians and that the average delay in diagnosis for those cases was 14 months.[5]

Foley and others internally reviewed the Armed Forces Institute of Pathology (AFIP) experience with breast cancer related malpractice claims in 1990.[6] Their study was drawn from 4,321 federal malpractice claims subjected to consultation by the Department of Legal Medicine at AFIP from 1980 through 1989. There were 80 claims related to the delayed diagnosis of breast cancer, and all were derived either from military medical services (77 cases) or other federal health agencies. The reviewers considered 56 (70 percent) of the study cases meritorious and substantiable malpractice claims. An error taxonomy was developed, and the most frequently encountered problems included failure to perform a biopsy (38 cases), especially when mammography was considered negative (19 cases), misreading of positive findings on mammography (5 cases), misreading of histopathology specimens (3 cases), inadequate biopsies (3 cases), and communication failures (3 cases). There were 68 closed cases, 51 (75 percent) with payment. Indemnification range from $6,000 to $1,000,000, with a median payment of $100,000 and a mean of $162,050.

Kern, in 1991, published a survey of all negligence trials involving the diagnosis of breast cancer retrieved through a national computerized legal database maintained by the West Publishing Company, **WESTLAW**, with opinions from both state and federal courts from 1971 through 1990.[7] The survey revealed 45 cases litigated in 38 states during those 20 years.

When patients' ages could be determined, 58 percent were less than 39 years old, the mean age was 40 years, and all were less than 59 years old.

The patient presented with a painless mass in 65 percent of cases. Pain, skin changes, and breast discharges exemplified additional symptoms that were reported, however, in more than 20 percent of cases. The diagnostic evaluation was limited to a physical examination in 51 percent of patients. Among the 20 mammograms that were obtained, 16 (80 percent) had been considered normal.

The average delay in diagnosis was 15 months. In 32 cases where the stage of disease at diagnosis was available, there were two cases at stage I, 22 at stage II, and the remainder at stage III or IV. In 12 cases, metastatic disease or death occurred by the time of litigation. The cases involving death included two patients who had initially presented when pregnant.

Kern concluded with an examination of case factors for claims resolved by an indemnification payment in excess of $500,000. In his opinion, those cases tended to involve the youngest patients, pregnant patients, and patients experiencing the longest delays.

Henderson and Danner published a review derived from their clinical and legal experiences highlighting certain "pitfalls" in the diagnosis and management of breast cancer.[8] They acknowledged that the treatment of this disease, whether by surgery, radiation, chemotherapy, or other measures, had been the source of some malpractice litigation. They were careful to stress, however, that the current frequency and severity of breast cancer malpractice claims over-

whelmingly rest with those concerning delayed diagnosis, "... the most common source of malpractice complaint among patients with breast cancer."

They also emphasized that a physician's desire to reassure a patient may prove troublesome. "This very admirable and laudatory trait leads to problems when such reassurance subsequently proves inappropriate. It is recommended that the physician explain how difficult breast cancer is to diagnose and assure the patient that no one will in any way be critical if the patient calls repeatedly because she is concerned .... For some, breast self-examination alone can be a source of anxiety."

Although screening patients may lead to malpractice claims, the authors noted how much more frequently the critical clinical encounter was the evaluation of a patient who reported the presence of a breast mass, especially when a biopsy was not performed. They specified what they considered adequate medical documentation upon clinical presentation for the patient's history and the physician's physical examination. Mammography may be obtained to evaluate the remaining ipsilateral breast tissue and the opposite breast, however, "with rare exceptions, the results of a mammogram should not dissuade a physician from proceeding with planned biopsy."

Similar to classic textbook exhortations,[9] the authors stipulated that "the diagnosis of breast cancer is only positively made by a microscopic analysis by a pathologist." They also advised practitioners on the appropriate responses to positive and negative biopsies, the variant results of cyst aspiration, the frequent need for needle localization for biopsy of isolated suspicious findings on mammography and measures to take to avoid the difficulties that these tiny lesions can cause with missed biopsies. Finally, they emphasized the need for clarity, comfort, counselling, and careful guidance during follow-up and re-evaluations.

THE 1995 PIAA STUDY

The Physician Insurers Association of American (PIAA), as previously noted in this publication, was organized in 1977 as a national representative body of those medical liability insurance companies owned or directed by doctors. There are now 47 medical liability insurance companies from across the United States that are constituent members of PIAA. Collectively, they insure more than half of the nation's private practicing physicians.

Since 1985, PIAA has maintained a central Data Sharing Project, a program created by 21 of the association's insurers, that collects a spectrum of data on all medical malpractice claims submitted to and closed by those companies to serve as a reliable and credible database for malpractice claims analysis and risk management. Presently, more than 117,000 claims and suits have been entered in that database. They include 35,700 paid cases with a total indemnity in excess of four billion dollars.

Since 1990, PIAA has annually published a series of focused reviews dedicated to particular categories of malpractice claims from the Data Sharing Project.

In 1995, the annual PIAA report addressed paid malpractice claims involving allegations of a delay in the diagnosis of breast cancer.[11] PIAA had previously published an analysis of the same type of claim in 1990. Breast cancer continued in 1995 to be the diagnostic condition for which a patient most frequently filed a malpractice claim against a PIAA member physician. Indemnification occurred in 44 percent of those claims, and the condition was second only to claims involving neurologically impaired newborns as the most expensive in terms of total indemnity paid. In the six-month interval prior to the 1995 report, the average indemnification for PIAA claims involving this condition exceeded $307,000.

There are 36 PIAA member companies that responded to a request to participate in the 1995 breast cancer study. They reported a total of 487 paid cases with incident dates after January 1985 that involved a delay in the diagnosis of breast cancer.

A key finding was that patients at presentation were relatively young, when the illness might not be suspected, when physicians might be less impressed by symptoms or findings, and when the disease can be more difficult to detect. More than 60 percent of patients were less than 50 years old, and their claims accounted for more than 71 percent of the total indemnity (Table 1).

PIAA STUDY: CLAIMANT'S AGE
n=487

Age	Number of Claims	Percentage	Percentage of Indemnity
20-29	31	6.4%	7.9%
30-39	119	24.4%	29.0%
40-49	150	30.8%	34.2%
50-59	111	22.8%	19.8%
60-69	56	11.5%	7.5%
70-79	14	2.9%	1.2%
80-89	2	0.4%	0.1%
unknown	4	0.8%	0.3%

TABLE 1

Most commonly, in 60 percent of cases, the patient detected the lesion herself. A mass without pain was reported in almost 50 percent of cases, but patients with symptoms of pain and tenderness, with or without a mass, were reported in more than 25 percent of cases.

Mammography was either negative or equivocal, when a lesion was present, in almost 80 percent of cases. These false negative or equivocal results appeared more frequently in women less than 40 years of age.

A total of 917 physicians and entities had been initially named in the 487 study cases, and payments were made on behalf of 675 defendants. The specialities with the highest frequency of paid claims reported were radiology, obstetrics gynecology, and family practice (Table2).

PIAA STUDY: DEFENDANTS
n=675

Defendant	Number of Claims	Percentage of Indemnity
Radiology	165	20.5%
Obstetrics/Gynecology	154	29.0%
Family Practice	113	13.5%
Surgical Specialties	97	17.0%
Internal Medicine	61	7.3%
Pathology	11	2.6%
Other Physician	31	3.5%
Corporation	30	5.6%
Hospital	13	1.0%

TABLE 2

There were awards negotiated by settlement in 462 cases, with an average indemnity of $282,244. There were nine resolutions by arbitration-mediation, and only 16 cases (3.3 percent) were tried to a jury verdict, where the average indemnity was $869,766 and the associated defense costs were approximately $101,0000 for each trial.

In contrast with the 1990 study, the 1995 survey reported an average length of delay in diagnosis that had increased from 12.7 months to 14 months, an increase of average indemnity of 36 percent from $221,524 to $301,460, and that radiologists were among the named defendants in 21 percent of cases as compared to 11.4 percent. The latter might reflect, over time, the burgeoning utilization of mammography for both diagnostic and screening purposes.

DISCUSSION

Given the relative youth of the patients involved in breast cancer malpractice cases, a striking dissonance should be apparent between the demographics of these claims and the epidemiology of the disease.

With breast cancer having been diagnosed in approximately two million women in the United States over the last decade, one question concerns the proper focus for the attention justifiably devoted to this somewhat special population of several hundred malpractice claimants.

Further, our society's courts are apparently convinced that medical science now knows the complete natural history of breast cancer and that medical treatments of proven efficacy exist for this malignancy when timely diagnosed. Those convictions, however, suspect, are applied by the courts to support imposing liability through an arguably contrived syllogism that time is always of the essence in diagnosing this disease and, therefore, a "lost chance" for survival is real, material, and precisely calculable.[7,12,13]

The courts, however, have not misled themselves. Their convictions find initial voice in the occasionally untempered declarations of national cancer-related charitable organizations, the proclamations of federal cancer research agencies, the edicts of national medical specialty associations, and the opinions of readily available expert witnesses.

Recent years have witnessed no change in the mortality rate for breast cancer, while the reported incidence of the disease has climbed steeply. These statistics could be interpreted as evincing the curative effectiveness of available treatments upon timely diagnosis. Conversely, the data may reflect, once again, the irresistible influence of lead-time bias.

Breast cancer that appears in patients who later file malpractice claims may be biologically different, or those patients could react to the threat of the disease with special host factors. In either context, the rote application of biostatistics derived almost completely from other breast cancer patients may not be justifiable.

Regardless, practitioners, as noted at the conclusion of the PIAA study, would be wise to take heed of certain tenets derived from these liability cases:

- Breast cancer can occur in relatively young patients, those in their 20's and 30's, more when pregnant.
- The clinical presentation of breast cancer includes patients with painful or tender breast lesions.
- Diagnostic mammography does not currently exist, and clinicians should consider those terms mutually exclusive.
- Breast cancer can be diagnosed now only upon the satisfaction of histopathologic criteria.
- The potential for false negative biopsies is heightened when evaluation small breast lesions, and special procedures, such as tissue specimen radiographs and early repeat mammograms, may be indicated.
- Careful counseling and assiduous reevaluation may be necessary to clarify the diagnosis of breast cancer, a disease where patient denial should be anticipated.

REFERENCES

1. Donegan WL. Evaluation of a palpable breast mass. NEJM. 1991;327:937-942.
2. Harris JR, *et al.* Medical progress: Breast cancer. NEJM. 1992;327:319-327.
3. *Cross v. Guthrey*, 2 Root (Conn) 90, 1 AM Dec 61 (1794).
4. Weiss RB. Consultant's corner: Delayed diagnosis of breast cancer. Legal Medicine Open File. 1993;93-2:19-20.
5. Haagensen CD. The diagnosis of breast cancer. In Haagensen CD (ed.). Diseases of the breast, 2nd ed. Philadelphia, PA: W.B. Saunders Co.;1971.
6. Foley HT, *et al*. Medical malpractice claims for delayed diagnosis of breast cancer: Analysis of 80 claims. Washington, DC: Armed Forces Institute of Pathology; 1990.
7. Kern KA. Causes of breast cancer malpractice litigation: A 20-year civil court review. Arch Surg. 1992;127:542-547.
8. Hender IC, Danner D. Legal pitfalls in the diagnosis and management of breast cancer. Hem Onc Clin North Am. 1989;3:823-842.
9. Wilson RE. The breast. In: Sabiston DC (ed.). Textbook of Surgery: The Biological Basis of Modern Surgical Practice, 13th ed. Philadelphia, PA: W.B. Saunders Co.; 1986.
10. Physician Insurers Association of America: Breast Cancer Study-June 1995. Washington, DC. Physician Insurers Association of America; June 1995.
11. Fisher ER. Pathobiologic considerations in the treatment of breast cancer. In: Grundfest-Broniatowski S., Esselstyn (CB (eds.). Controversies in Breast Disease: Diagnosis and Management. New York, NY: Marcel Decker Co.; 1988.
12. Spratt JS, Spratt SW. Medical and legal implications of screening and follow-up procedures for breast cancer. Cancer. 1990;66 Suppl 6:1351-1362.

MEDICAL PRACTICE GUIDELINES: IS COOKBOOK MEDICINE HERE?

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After a 74 year old woman died in Illinois of breast cancer, her husband and the executor of her estate brought a suit that claimed medical malpractice on the part of one of her doctors.[1] The plaintiffs specifically alleged that the physician had violated the standard of care when he failed to recommend or order a screening mammogram for the patient during the three years prior to the diagnosis of her breast cancer when he served as her general physician. Medical experts for both sides based their testimony regarding whether the standard of care was breached on guidelines established by the American Cancer Society (ACS), the National Cancer Institute, the American Medical Association (AMA) and the American College of Physicians. The defendant argued that the ACS guidelines, as well as recommendations made by other medical organizations, were only "signposts" to assist an internist in practice and were clearly not the "standard of care."

In Illinois, the standard jury instruction states "the only way the jury may decide whether a defendant possessed and applied the knowledge and used the skill and care which the law required of him is from expert testimony (and) (or) evidence of professional standards of conduct."[2] Because the experts disagreed as to the impact of the various guidelines, the trial court exercised its discretion and excluded them as evidence of professional standards. A state appellate court reversed that decision and remanded the case for a new trial. The court declared that the guidelines, although contested, should be admitted as evidence of professional standards. In summary, a jury would have to hear all the arguments and determine the weight to be granted the evidence. In the context of this legal decision, some physicians may view practice guidelines as the self-created noose by which they hang themselves in court.

During the second presidential debate in October 1992, candidate Bill Clinton said, "I've recommended that our doctors be given a set of national practice guidelines and that if they follow those guidelines, that raises the presumption that they didn't do anything wrong." Thus, the concept of medical practice guidelines, or practice parameters, as the AMA prefers, was added to the political porridge.

What are practice guidelines? How are they developed? What are the legal implications of practice guidelines? How will they affect medical practice now and in the future? These are questions posed by physicians with increasing frequency.

Practice guidelines are defined as "systematically developed statements of recommendation for patient management to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."[3] The AMA has embraced the concept of practice guidelines, and, in 1989, its Office of Quality Assurance and Medical Review began publishing the *Directory of Practice Parameters: Titles, Sources, and Updates*.[4] This title identified 700 published practice guidelines in all fields of medicine. The 1994 edition of the *Directory* contains over 1500 references, identifies 240 recently published guidelines and another 310 in development. Practice guidelines are not written to last forever, and the 1994 *Directory* also lists 150 guidelines that have been recently withdrawn by their sponsoring organizations. In addition, the names and addresses of 69 sponsoring organizations which have supported the development and publication of the guidelines are also referenced. These organizations span a range of medical specialty societies, from the American Association of Neurological Surgeons through the American Society of Colon and Rectal Surgeons. Further, they include government agencies such as the National Institutes of Health, and the Federal Agency for Health Care Policy and Research, philanthropic organizations such as the National Kidney Foundation, and private research firms such as the RAND Corporation.

Dr. David Eddy of Duke University has noted that practice guidelines are not new phenomena and that many textbooks of medicine are full of them under the "treatment" rubrics.[5] He notes that many have become "grandmotherly" adages; to treat frostbite, for instance, the physician is advised, "freeze in January, operate in July."[6] What is novel is that practice guidelines are being used today not as suggestions to practitioners but as benchmarks for regulatory activities, such as utilization review, quality assurance, credentialing, cost containment, and malpractice litigation.

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A driving impetus to formalize and publish officially sanctioned practice guidelines occurred in the mid 1980's and resulted from the confluence of three forces. The predominant force was the rising cost of health care to the federal government. Diagnosis related group payment had been successfully applied to Medicare hospital expenditures. The fastest growing component of the federal health care bill then became physician payments under Medicare. Congress developed a keen interest in scrutinizing physician services for medical necessity and effectiveness and held provider reimbursement in the balance.

Secondly, an increasing awareness of medical outcomes research had begun to influence health care policy debates. In the early 1970's Dr. John Wennberg from Dartmouth Medical School documented substantial geographic variations in the rates of surgical procedures, which occurred in spite of the presence of nearly homogeneous populations. In one of the earliest studies, the rate of tonsillectomy varied from 13 per 10,000 residents in one Vermont community to 151 per 10,000 in another.[7]

Subsequently, researches began to construe statistically significant elevations in surgical rates as potential indicia of inappropriate surgery, and studies were designed to test clinical appropriateness of treatments. In a 1987 RAND Corporation study of Medicare patients, 17% of coronary angiography, 17% of upper gastrointestinal tract endoscopies, and 32% of carotid endarterectomies, adjudged by predetermined selection criteria, were considered inappropriate treatment.[8] The issue of inappropriate care became the third force driving governmental interest in clinical practice guidelines.

With potential reimbursement and public determination of appropriate clinical care at stake, many medical specialty organizations quickly realized an interest in publishing clinical practice guidelines. This was a new endeavor for some, but for others, such as the American College of Cardiology, this was a continuation of activities commenced years earlier.

Congress formalized the process on the federal level in 1989 when it established the Agency for Health Care Policy and Research (AHCPR). The stated purpose of the agency is to enhance the quality, appropriateness and effectiveness of health care services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical practice and in the organization, financing and delivery of health services.[9] The AHCPR is part of the United States Public Health Service and functions at the same administrative level as the Center for Disease Control and the National Institutes of Health. A component of its mission is the development and promotion of clinical practice guidelines.

The AHCPR has published several practice guidelines. The first was published in March 1992 and dealt with postoperative pain management. It was published in three forms: a definitive scientific paper, a reference summary for physicians, and a patient pamphlet. Reaction by providers and the public appeared quite favorable, as with the next two federal guidelines, devoted to urinary incontinence and decubitus ulcers. The following two guidelines, regarding the evaluation and treatment of cataracts and mental depression, however, stimulated some controversy. For instance, optometrists complained about the conclusion of the cataract panel that postoperative care be performed only by operating ophthalmic surgeons, and psychologists strongly objected to medication-oriented therapies favored by the depression guideline.[10]

State legislatures have also passed laws dealing with practice guidelines and their implementation.[11] Minnesota and Washington have enacted health care reform legislation that created commissions to develop and promulgate practice guidelines to minimize unnecessary and ineffective care. Florida's statute specifically addresses the issue of cost effectiveness as well as the quality of care.[12] Maryland's new health care reform package establishes a multidisciplinary commission, including three physicians, to research and develop practice guidelines.[13]

The medical community has often voiced strong reservations about the publication of practice guidelines, especially with regard to their legal implications. Physicians' greatest fear is that a technical deviation from a guideline will be construed as negligence *per se*, conclusive evidence alone, or "by itself", of legally substandard care.

No jurisdiction has permitted a deviation from a practice guideline to be equated with conclusive evidence of malpractice. Some jurisdictions, such as Illinois, will permit the admission of a relevant guideline as one piece of evidence but not as the definitive evidence of applicable standards of care.

Most often, those jurisdictions also insist that the published guidelines cannot be introduced in the form of

documented evidence alone. They compel the presence of an expert witness to introduce the guidelines to the judge or jury, to substantiate their authenticity and their relevance, to explain their contents, and to be subjected to potential cross examination. Further, defendants retain their rights to present evidence that the proffered guidelines were irrelevant to the clinical circumstances, that any deviation whatsoever had occurred, or that the reasonable practice of medicine embraced the care as rendered, regardless of the guidelines or any technical deviation.

The idea that adhering to practice guidelines could provide a shield against liability in malpractice cases has helped overcome some physicians' antipathy toward their publication.

Maine, in its Medical Liability Demonstration Project (the Project), is currently experimenting with giving conclusive effect to practice guidelines for the defense of malpractice claims.[14] The Project initially funded the development of practice parameters or guidelines in four medical specialties: obstetrics and gynecology, radiology, emergency medicine and anesthesiology. State legislation gives those guidelines the force and effect of law. The rationale of the Project is that "practice guidelines provide a means of using health care resources more efficiently, discouraging the practice of defensive medicine, improving the quality of medical care, reducing the incidence of iatrogenic harm, and rationalizing medical malpractice litigation."[15] The guidelines published to date are literally checklists, almost like recipes for appropriate medical care. They have been in effect since 1991. What would have once been abhorrent to some physicians has become tolerable, even desirable, in Maine, because the legislature has created a nearly irresistible incentive for physicians-malpractice immunity.

In a medical malpractice action against a physician participating in the Project, only the physician may introduce the practice guidelines into evidence. As an affirmative defense, the physician must then prove compliance with the guideline. Once the guideline is introduced, the plaintiff may offer rebuttal evidence to support noncompliance. If the jury concludes that the practice rendered complied with the published guideline, the physician cannot be found liable for malpractice. While some physicians remain dissatisfied with the cookbook nature of Maine's guidelines, few quarrel about the obvious benefit of liability protection.

Similar to Maine, legislation in Minnesota cites adherence to approved practice guidelines as an absolute defense to malpractice charges, allowing physicians to employ them to support a defense of care rendered within standards but prohibiting their use by plaintiffs to evince substandard care.[16,17] Florida included liability protection in its clinical guideline statute as an effort to reduce the expense of defensive medical practices.[18] Maryland specifically prohibits either plaintiff or defendant from citing practice guidelines in malpractice cases, while the state of Washington specifically encourages the use of guidelines as evidence in medical liability cases. At the national level, no legislation exists that links practice guideline adherence to protection against claims of negligence.

Empirical evidence that clinicians are applying practice guidelines to patient care is sparse. Despite the growing interest in practice guidelines at the policy level, it appears that only half of physicians use the guidelines available with any regularity. In 1994, the *American Medical Association News* reported that hospital-based specialists were more likely to use guidelines than office-based generalists.[19] The *AMA News* also reported that an American College of Physicians survey, scheduled for publication in January 1996, has found a generally favorable reaction by physicians to guidelines. Two-thirds of the internists surveyed considered guidelines convenient sources of advice and good educational tools. A similar proportion agreed that guidelines could improve the quality of care. Only one-fourth objected to guidelines because they represented "cookbook" medicine, and a slightly smaller proportion objected to them on the grounds of their reducing physician autonomy. Less than one-fifth of those surveyed thought that guidelines would reduce malpractice suits.

Practice guidelines are now a familiar fixture on the American medical scene. Their theoretical ability to improve quality of care, reduce inappropriate care, minimize differences in geographic usage, and limit malpractice exposure has captured the imaginations of candidates, legislators, policy makers and quality reviewers. Clinicians expected to apply them have been cautiously slower with their embrace.

REFERENCES

1. *Kramer v. Milner*, 639 N.E.2d 157 (Ill. 1994).
2. IPI Civil 3d.No.105.01 (3d Ed. 1990)
3. Institute of Medicine. Clinical Practice Guidelines: Directions for a New Program. Washington, DC: National Academy Press; 1990.
4. Office of Quality Assurance and Medical Review, American Medical Association. Directory of Practice Parameters: Titles, Sources, and Updates. Chicago, IL: American Medical Association; 1994.
5 Eddy DM. Clinical decision making: From theory to practice. Practice policies—What are they? JAMA. 1990; 263:877-878, 880.
6. Berkow R, Fletcher A. The Merck Manual of Diagnosis and Therapy, 15th ed., Rahway NJ: Merck Sharp & Dohme Research Laboratories: 1987.
7. Wennberg J. Dealing with medical practice variation: A proposal for action. Health Aff. 1984;3:6.
8. Chassin MR, Kosecoff J, *et al*. The Appropriateness of Use of Selected Medical and Surgical Procedures and its Relationship to Geographic Variations in Their Use. Ann Arbor, Mich: Health Administration Press; 1989.
9. 42. U.S.C. § 299.
10. Leary, "Doctors Urged to Look for Signs of Depression", NY Times, Apr. 21, 1993, at C12.
11. Oberman, "States Race to Whip up Practice Guidelines; Too Many Cooks?" Am. Med. News, Oct. 4, 1993, at 1.
12. FLA. STAT. ANN § 145.65 (west 1995).
13. MD. HEALTH-GEN. CODE ANN. § 19-1602 (West 1995).
14. ME. REV. STAT. ANN. TIT. 24, § 2971-79 (West Supp. 1994).
15. Kuc GW. Practice parameters as a shield against physician liability. J. Contemp. Health Law & Policy. 1994; 10:439.
16. MINN. STAT. ANN. § 145.65 (West 1995).
17. Hyams AL, *et al.* Practice guidelines and malpractice litigation: a two way street. Ann Intern Med 1995; 122:450-455.
18. FLA. STAT. ANN. § 408.02 (West 1995).
19. Oberman, "AMA Panel on Guidelines Sorts Good from Misguided", Am. Med. News, Jan. 10, 1994, at 1.

EDITOR'S NOTES

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NECK PAIN

by STEPHEN V. MAWN, M.D., J.D.,
CDR, MC, USN

Neck pain is a ubiquitous symptoms and a frequent reason for patients to seek medical care. A recently reported random survey of 10,000 adults found that 34 percent of 7,648 respondents had experienced "troublesome neck pain" during the previous year.[1] Chronic neck pain, defined as neck pain lasting more than six months, occurred in 17 percent of women and 10 percent of men. This corresponds with an earlier study of 8,000 adults in which a "chronic neck syndrome" was identified in 13.5 percent of female respondents and 9.5 percent of males.[2]

Typically, neck pain does not indicate a serious medical condition. Most patients with neck pain do not require an evaluation by a neurosurgeon or cervical spine neuroimaging. Their conditions frequently are self-limited and require only symptomatic treatment, if any. Some patients, however, manifest serious cervical spine pathology by complaining of neck pain. Similar to other severely ill patients who present with common complaints, the timely identification of patients with neck pain who harbor serious disease can be crucial to successful treatment and optimal clinical outcome.

Two professional negligence claims from the case files of the Department of Legal Medicine at the Armed Forces Institute of Pathology, resolved with substantial payments, are presented to illustrate a number of important points.

CASE 1

A 62-year-old man, with a history of diabetes mellitus and degenerative spine disease, presented to the primary care clinic of a federal hospital with a ten day history of fever, as high as 105° F, and sharp lower neck pain with bilateral shoulder discomfort. He had also experienced URI symptoms and was "still productive of brown sputum." When examined by a physician, the patient was afebrile, his lungs were clear, and his cervical spine demonstrated a full range of motion. There was a white blood count of 14,500 with a left shift, and a chest x-ray was unremarkable. The physician diagnosed acute bronchitis and prescribed an eight day course of antibiotics. No follow-up was specified.

Two weeks later, the patient was evaluated by the same provider for persistent neck, upper back and bilateral shoulder pain. The physician noted that the patient had experienced chronic cervical pain "since the 1950's" but that his condition had worsened during the previous two years, markedly so in the previous two months. Finding marginally decreased motor strength in the patient's upper extremities, where deep tendon reflexes were absent, the physician diagnosed acute and chronic cervical pain with diabetic peripheral neuropathy. Cervical spine x-rays were performed that day. Cervical spine CT was scheduled for one week later.

The plain films were interpreted as demonstrating "hypertrophic degenerative changes" only. Later review disclosed, however, a destructive process at the C6/7 interspace involving the superior aspect of the C7 vertebral body and the inferior aspect of the C6 vertebral body. There is no indication that the attending physician either reviewed the x-rays or received a contemporaneous report. Late in the day of this second evaluation, the patient sought treatment from a local civilian physical therapist. When cervical traction partially relieved the patient's shoulder pain, the physical therapist urged him to consult a neurosurgeon for a possible disc herniation.

Within several days, a neurosurgeon in private practice, having found "severe cervical spasms" and "mild weakness in [the] upper and lower extremities," advised the patient to present himself to a larger federal medical center nearby and "demand to see a neurosurgeon." The civilian neurosurgeon later stated that he offered to admit the man to a local hospital but that the patient insisted on seeking care through the federal system.

The following day, the patient presented to the emergency department of the federal medical center and reported severe lower neck and shoulder pain. He was afebrile. Discomfort was elicited upon palpation of the "mid-lower thoracic spine." Motor strength in all extremities was documented as "good" and deep tendon reflexes as "wnl." A hilar mass was suspected on chest x-ray, and the patient was referred to the primary care clinic for further care, with a recom-

mendation that he undergo a chest CT. A repeat chest x-ray was performed the next day, and a reviewing physician ruled out a hilar mass and determined that a **chest** CT was not indicated. Realizing that a cervical spine CT remained scheduled at the smaller federal hospital, the physician diagnosed "probable DJD. R/O herniated disc", scheduled an MRI of the cervical spine to be performed in three weeks, and requested neurosurgical consultation on a routine basis.

Cervical spine CT was performed the next day. The radiologist's written report noted "a mottled appearance to the C6 vertebral body" and that "osteolytic lesions can not be excluded." There is no indication that the physician who ordered the scan reviewed the study or the written report.

Three days later, the patient presented to the emergency department of a private community hospital and complained of increasing neck pain. The neurosurgeon who had previously evaluated him noted that the patient's upper extremity weakness had "worsened", especially in the intrinsic muscles of his hands. Biceps and triceps reflexes were absent bilaterally. Following admission to the hospital, the patient underwent diagnostic studies that included cervical spine x-rays, an MRI of the cervical spine and a radionuclide bone scan. These strongly suggested osteomyelitis of the lower cervical vertebrae, cervical diskitis, and an epidural abscess.

The patient underwent surgery 26 days after initial clinical presentation. Epidural and prevertebral abscesses were drained, and a C6/7 discectomy with an anterior interbody fusion was performed. Cultured surgical specimens grew *Escherichia coli.* No additional neurologic examinations were documented during the hospitalization. The patient was discharged home on his tenth postoperative day.

A spine stabilization procedure was required three months later. Perioperatively, the patient was reported to have experienced mild weakness confined to wrist extensors and hand intrinsic bilaterally. These deficits were again detected upon neurologic examination two and a half years after the original surgery.

In time, the patient submitted a malpractice claim alleging that, as a result of a negligent delay in diagnosing his spinal abscess, federal health care providers had caused him to suffer permanent neurologic injury. Specialty reviewers concluded that the care rendered was substandard, and the claim was settled administratively.

COMMENTS

Infection directly invades the epidural space from a local process, such as osteomyelitis, or hematogenously from a distant focus, such as a skin sore.[3] Urinary tract infections, peridontal abscesses, pharyngitis, pneumonia, and mastoiditis have also been implicated as distant sources for sepsis that results in a spinal epidural abscess. Symptoms in patients with untreated spinal epidural abscess have been described as progressing through four stages: spinal ache, root pain, weakness, and paralysis.[4] In on report, there was a history of antecedent or concurrent infection in three-quarters of the patients.[4] Fever exceeded 101°F in 14 of 18 patients in one retrospective study, and a mean peak temperature of 103°F was reported in another.[5,6]

Case 1 was somewhat unusual since the abscess was located in the anterior cervical spine and the causative organism was *Escherichia coli*. Typically, spinal abscesses are located posteriorly in the thoracic or lumbar spine, due to the greater width of the epidural space there.[3] *Staphylococcus aureus* is the organism most often involved, although *Mycobacterium tuberculosis* has been reported in some series as the responsible agent for as many as one-fourth of cases.[7] Interestingly, although anterior abscesses are uncommon, the majority of them occur with cervical osteomyelitis, as in the case presented.[6]

In one study undertaken before neuroimaging was widely available spinal abscess pain was present for a mean of 16 days before hospitalization.[7] Timely diagnosis of a spinal epidural abscesses difficult for several reasons. First, the disease is relatively rare.[3] In addition, a practitioner must entertain the diagnosis while much more common causes of neck pain, such as degenerative joint disease or myalgias, operate as clinical confounders. Another reason for delay is that this rare diagnosis must be suspected and pursued by primary health care providers who may have never encountered a case clinically. Modern pressures on

providers to control costs by ordering diagnostic studies less frequently, especially expensive ones like neuroimaging, and seeking consultations more selectively may aggravate diagnostic delay.

In the case presented, those factors may have all played some role in delaying the diagnosis of the patient's cervical abscess and associated vertebral osteomyelitis. More importantly, however, significant errors in fundamental clinical skills were committed. They include inadequate evaluations and follow-up, radiographic misinterpretation, miscommunication between providers, and problematic documentation. Each materially contributed to prolonging the time spent before a difficult diagnosis was confirmed.

Another potentially devastating disease process that often presents with localized a traumatic neck pain progressing to radicular pain, then weakness, is a tumor.[8] A recent trial judgment against the United States involved a woman who had experienced neck, upper back and upper extremity pain, while manifesting ambiguous neurologic signs for months.[9] She was variously diagnosed with degenerative joint disease, tension headaches and multiple sclerosis. Ultimately, a foramen magnum meningioma was detected.

Despite the widespread availability of neuroimaging, tumors of the foramen magnum still evade early diagnosis.[10] In a review of 102 cases, two-thirds presented with neck pain and nearly 60 percent with dysethesias.[11] In this patient's case, difficult diagnosis was made impossible by incomplete and uncoordinated evaluations that were rendered at different facilities by different providers, each of whom, among other things, missed the tumor on the inferior cuts of a cranial MRI obtained to confirm multiple sclerosis.

For reasons similar to those that contribute to the delayed diagnoses of spinal epidural abscesses, tumors in our around the cervical spine are frequently recognized only after permanent neurologic injury occurs. Clinical errors only exacerbate the diagnostic delays.

CASE 2

Two weeks after falling, a 45-year-old man presented to the outpatient department of a federal health care facility complaining of right upper extremity pain with intermittent numbness and tingling. The medical record also noted "upper thoracic spinal pain." Motor and sensory examinations of the upper extremities were recorded as normal. Cervical spine x-rays demonstrated a posterior spur at C5 and a narrowed disc space at C5/6.

Four weeks later, the man presented in the late evening to the emergency department of the same facility. On a preprinted form, the admitting nurse indicated that the patient was ambulatory on arrival. In a SOAP note, she wrote for subjective complaints that "My pain has been here since '71 and I want it gone" and for the objective findings "Helicopter crash and C-spine injury—c/o weakness, tingling in extremities." The assessment was "ETOH overload—back pain", and the plan was "Eval."

The evaluating physician, a third-year internal medicine resident, recorded that the patient had been in a helicopter accident 15 years previously and had suffered a "C-spine injury." He noted that the patient was complaining to him of upper extremity tingling bilaterally and weakness of his lower extremities but denying bowel or bladder incontinence. The patient also reported severe neck and shoulder pain for which he had been drinking considerable amounts of alcohol and taking acetaminophen with codeine. The available medical record does not specify a time of onset for the patient's symptoms.

According to the physician, the patient had entered into a physical altercation with his wife while waiting to be evaluated, and the patient had also struck him. The resident specifically recalled helping the patient walk to a seat in the waiting room of the emergency department.

When examined, the patient was initially combative and verbally abusive. He later calmed down. His breath smelled strong of alcohol. Neurologic examination was notable for mild weakness in all upper extremity muscle groups tested and for lower extremities that "would not move at all." Because there was ambulation with assistance earlier, the physician concluded that the patient was "not making any effort." No further neurologic testing by that provider was documented. There is no record of deep tendon reflexes or a sensory exam. Laboratory studies were

unremarkable except for a blood alcohol of 256 mg./dl. An on-call neurosurgical resident advised a re-evaluation when the patient was sober and, if true weakness existed, a cervical spine MRI.

The next medical record entry is a note by a consulting neurologist in the middle of the following morning. A more extensive history, with a chronology of the patient's neurologic symptoms, is documented. Pain and tingling in the neck and arms had begun three days earlier. During the previous evening, approximately an hour before presenting to the emergency department, developed "increasing weakness in his legs such that he could not bear weight." Examination revealed a C7 quadriplegia with a C8 pin-prick level. Intravenous dexamethasone was administered, and the patient underwent an emergency cervical spine MRI. Two large disc herniations at C4/5 and C6/7 were demonstrated.

The patient was brought to surgery six hours later, and a C6/7 anterior discectomy with fusion was performed. His neurologic exam revealed no change postoperatively and remained stable two years following surgery.

A federal malpractice claim alleged that a failure to properly diagnose and treat a neurologic emergency had resulted in the patient's quadriplegia. A large structured settlement was eventually negotiated.

COMMENTS

Cervical disc disease does not always present as a nagging chronic condition. The first case report of cervical disc surgery in 1892 involved a young man who developed progressive weakness of all extremities after a fall.[12] Two authorities in spinal disease have written that "[a]lthough acute and chronic cervical disc degeneration are likely to be stages in the same degenerative process, they must be handled separately in clinical discussion."[13] These authors have also noted that "the syndrome of acute cervical disc herniation is attended by severe pain that leads to voluntary immobilization of the neck" whereas "the pain of chronic disc degeneration, though at times severe, may wax and wane, sufficiently to allow those affected to maintain a relatively normal activity schedule."

Obtaining a reliable history in severely traumatized patients is often hindered by head injuries, drugs, or alcohol. Similarly, a physical examination, particularly a neurologic examination, is ideally performed on a cooperative, intelligent and articular patient, one rarely brought to an emergency department following major trauma.

The initial delay in diagnosing an acute disc herniation in Case 2 resulted from a drastic abridgement of history taking and physical examination due to understandable, yet problematic, factors. Confirming this diagnosis by MRI three hours after it was suspected may seem reasonable to practitioners accustomed to their patients waiting weeks for such a study. The ensuing three and one-half hours before commencement of spinal cord decompression probably resulted from an extremely busy operating room suite. Although each segment in the sequence can be explained, a 20-hour delay between presentation and spinal cord decompression, when the patient progressed from ambulation to quadriplegia, would not likely be considered consistent with acceptable care by professional peers or a civil court.

Neck pain that follows its two most common traumatic antecedents, motor vehicle accidents and falls, usually emanates from soft tissue injuries and is relatively innocuous. One article, premised upon data from a Swiss accident insurance firm, reported that 87 percent of post-traumatic cervical complaints were the result of soft tissue injuries.[14] Nevertheless, the American College of Surgeons, recognizing the potential devastation wrought by underestimating serious neck injuries, urges participants in its Advanced Trauma Life Support course to "[a]ssume a cervical spine fracture in any patient with multisystem trauma."[15]

In a review of 300 cervical spine fractures, 100 were initially missed in the emergency department.16 Delayed diagnoses most commonly occurred in those patients with serious head injuries, those with other fractures or multiple injuries, and those who were intoxicated.

Recently, two large settlements occurred in federal cases that involved patients with persisting neck pain after odontoid fractures were not properly diagnosed. Misinterpretations of x-rays, along with an unwillingness to reconsider initial clinical misimpressions, were at the heart of liability.

FINAL COMMENTS

In the cases presented, neck pain, a common symptom in general medical practice, appeared as a harbinger of uncommon but serious disease processes. As such, these cases share particular characteristics with similar clinical situations frequently subjected to allegations of medical malpractice for delayed diagnosis.

To appreciate disease progression, a skilled practitioner blends critical features from a directed history with occasionally subtle signs from a focused physical examination. Under certain circumstances, serially repeated examinations should be performed. Alternative diagnoses, some relatively rare, are then reasonably considered. Appropriate diagnostic studies and specialty consultations to confirm those impressions may, in turn, be justifiably obtained. Omitting or improperly abridging a step in this fundamental process will likely blind a practitioner to all but the most common diagnoses and significantly increase the possibility that a difficult diagnosis will be inordinately delayed.

REFERENCES

1. Bovim G, *et al*. Neck pain in the general population. Spine. 1994; 19:1307-1309.

2. Makela M, *et al*. Prevalence, determinants and consequences of chronic neck pain in Finland. Am J Epidemiology. 1991; 134:1356-1367.

3. Verner EF, Musher DM. Spinal epidural abscess. Med Clin North Am. 1985; 69:375-384.

4. Heusner AP. Nontuberculous spinal epidural infections. NEJM. 1948; 239:845-854.

5. Yang SY. Spinal epidural abscess. New Zealand Med J. 1982; 95:302-304.

6. Baker AS, *et al*. Spinal epidural abscess. NEJM. 1975; 293:463-468.

7. Kaufman DM, *et al*. Infectious agents in spinal epidural abscesses. Neurology. 1980; 30:844-850.

8. Long DM. Cervical cord tumors. In: The Cervical Spine Research Society (eds.). The Cervical Spine. Philadelphia, PA: J.B. Lippincott Co.; 1983.

9. *Kronbach v. United States*, No. 921-820-Civ.-J-16 (M.D. Fla. Feb. 1, 1993).

10. Wagle VG, *et al*. Diagnostic potential of magnetic resonance in cases of foramen magnum meningiomas. Neurosurg. 1987; 21:622-626.

11. Meyer FB, *et al*. Benign tumors of the foramen magnum J. Neurosurg. 1984; 61:136-142.

12. Taylor AR, Collier J. Case report. Brain. 1901; 24:532.

13. Rothman RH, Simeone FA. The Spine, 2nd ed. Philadelphia, PA: W.B. Saunders Co.; 1984.

14. Dvorak J, *et al.* Cervical spine injuries in Switzerland. J Manual Med. 1989; 4:7.

15. American College of Surgeons. Advanced Trauma Life Support Course for Physicians. Chicago, IL: American College of Surgeons; 1989.

16. Bohlman HH. Acute fractures and dislocations of the cervical spine: An analysis of 300 hospitalized patients and review of the literature. J Bone Joint Surg. 1979; 61A: 1119.

ANSWERS TO CME QUESTIONS

1. C	6. D	11. C	16. D
2. B	7. D	12. D	17. E
3. E	8. C	13. D	18. D
4. E	9. D	14. E	19. A
5. C	10. B	15. E	20. B

EXPERT TESTIMONY IN MEDICAL MALPRACTICE LITIGATION
by JENNIFER A. DOWD, J.D.

A woman undergoing minor foot surgery sustained a third degree burn when a surgical technician inadvertently placed a hot instrument on her leg. A lawsuit, alleging failure to properly supervise the technician, was filed against the attending podiatrist. The trial court granted summary judgment for the defendant. The court concluded that there was insufficient evidence to find the surgeon at fault for the injury, since the plaintiff had not offered any expert testimony regarding the "roles and responsibilities of surgeons and hospital staff." An appellate court affirmed.[1]

In another recent case, a man sustained a broken jaw in a motorcycle accident, and then filed a malpractice sui t against the plastic surgeon who had repaired it. At trial, the defendant objected when the plaintiff offered the testimony of a dentist as his expert. The defendant argued that, by state statute, a dentist does not qualify to testify regarding the standard of care for plastic surgery. Ultimately, an appellate court agreed with this argument and reversed the trial court's decision to allow the dentist's opinion.[2]

Expert opinions are critical to the resolution of legal disputes involving medicine, especially when professional negligence is alleged. To prove their allegations, medical malpractice plaintiffs are usually obliged to provide the court with expert testimony. In response, defendant practitioners routinely rebut such testimony by offering opinions from their own experts.

Problems can arise when no expert testimony is offered, or when the proffered expert lacks expertise in the defendant's specific area of professional practice. There can also be difficulties when the basic theory supporting an expert's testimony has neither demonstrated sufficient reliability nor gained broad acceptance within the scientific community. Both legislation and case law exist that address these problems. Understanding when an expert is required and what an expert "opinion" should include can be valuable to practitioners who become involved in litigation.

ESTABLISHING MEDICAL MALPRACTICE THROUGH EXPERT TESTIMONY

Experts testify to assist the trier of fact, either a judge or jury. Their testimony must be relevant to the issues being tried and should reference information outside the realm of common knowledge. Meteorologists testify about the phases of the moon on the night a burglary occurred. Ballistic experts explain how close the gun was to the victim or from what direction it was fired. Similarly, health care practitioners may provide information regarding medical sciences or clinical practice.

By definition, a legal claim of medical malpractice demands a determination that a medical practitioner breached the duty owed to a patient to render adequate care. An opinion from a medical expert can transform the suspicions of an injured patient or disgruntled family member into a cognizable complaint. In addition, all states, either by statute or case law, require that evidence of some form be provided at trial regarding the professional standard of care governing the physician's duty and how that standard was breached. This is best accomplished through an expert witness who is a purported peer of the defendant and who qualifies to explain the technical aspects of the case to the trier of fact.

For every rule there are exceptions, and despite the need for an expert's testimony generally, not all medical claims require such opinions. The doctrine of *res ipsa loquitur* ("the thing speaks for itself") may arise where an error is considered so obvious that it supports a conclusion of negligent practice without the need for expert testimony.

Common fact patterns in medical practice where the doctrine has been applied include cases where a sponge or instrument is left in a surgical cavity or the wrong organ or body part is removed. While *res ipsa* does not conclusively prove that negligence occurred, it does amount to legal evidence sufficient to avoid case dismissal.

Res ipsa claims notwithstanding, the vast majority of medical malpractice claims require competent expert testimony. "Competency" is within the discretion of the trial judge, as guided by relevant statutory or case law directives. The Federal Rules of Evidence state that adequate "knowledge, skill, experience, training or education" is necessary for an expert to qualify, while individual states can require clinical experience, or have a locality requirement.[3] It is imperative to know the criteria for the jurisdiction where the suit is litigated.[4]

Generally, a medical malpractice negligence claim is filed when an injured patient or family member becomes convinced that improper medical care has caused an injury. In court, an expert opinion is required to establish: 1) the standard of proper professional skill or care; 2) a failure by the defendant to conform to that standard; and 3) a causative link between that breach and the patient's injury. Such testimony can only be established by someone deemed knowledgeable regarding the applicable standard of care, specifically, a professional peer.

At the outset, a case was presented in which no expert opinion was offered. The claim regarding the burns inflicted by a hot surgical instrument was based on the legal concept for vicarious liability. The podiatrist was alleged to be liable through the negligence of an erring assistant whom he failed to supervise. Unfortunately, the plaintiff offered no expert testimony to establish what the doctor's supervision should have entailed. Since the standard of care was never defined, the trial court dismissed the suit. The court determined that establishing the podiatrist's supervisory responsibilities did indeed require an expert's opinion, since those responsibilities are not within the common knowledge of a layperson. Without the missing testimony, the plaintiff did not have sufficient evidence to prove her case.

More common is the case where an expert is offered by the plaintiff and prepared to testify but is arguably not qualified. Aside from fraud, an expert can fail to qualify either because the state's "locality rule" prohibits the testimony or because the witness' area of expertise is different from that of the defendant.

WHO MAY TESTIFY

Historically, care rendered by a medical malpractice defendant was measured legally against the professional standards of locality where the defendant practiced. An important rationale for holding physicians to local standards was to protect rural general practitioners. Otherwise, they might be held to the same standards of practice as urban physicians, who had substantially greater access to technology, research, and consultative opinions. Consequently, an expert called to testify against the defendant physician was required to be from the same locality and, therefore, familiar with the existing standards in that region. As medicine and communication advanced, these theoretical foundations for the "locality rule" began to erode, particularly for defendants involved in specialty medical practice.

In one notable case, the Supreme Court of Mississippi expressly replaced the precedent "locality rule" in 1985 with a national standard for professional care.[5] There, a patient underwent an exploratory laparotomy for a suspected bowel obstruction, was moved from the recovery room to a private room, and expired. At trial in the subsequent wrongful death suit, the testimony of two Ohio physicians was offered to prove negligence in postoperative monitoring. The trial court barred the testimony of these out-of-state experts as violative of the locality rule. The experts, applying a *national standard* of professional skill and competence, would have testified that the defendant breached an applicable standard of care.

On appeal, the state supreme court reversed and decided that the proffered testimony should have been allowed. A common standard was found to apply to all physicians practicing in the same specialty throughout the United States, and the court pointed out that patients should expect similar postoperative care regardless of whether they were "in Cleveland, Ohio, or Pascagoula, Mississippi."

The now common practice of holding local physicians to a national standard enlarged the pool of potential expert witnesses. Applying a national standard allows any competent and qualified physician in that

specialty to offer an opinion as to the adequacy of care rendered by a local physician.

A 1995 decision from the Supreme Court of Michigan illustrates this relaxation of admissibility.[6] The mother of a deceased patient brought a medical malpractice claim after her son suffered cardiac arrest. The plaintiff's expert witness was an internist from Philadelphia and a member of the medical school faculty at the University of Pennsylvania. He testified about the applicable standard of care for residents and interns generally but professed no knowledge of the standards as practiced in Detroit. A jury verdict for the plaintiff was reversed by an intermediate appellate court, because the expert had not been properly qualified. The Supreme Court of Michigan disagreed and reversed the appellate decision. The opinion reiterated that, for Michigan, "the standard of care for general practitioners is that of the local community or similar communities and is nationwide for a specialist." The court concluded that the expert's curriculum vitae served as adequate qualification for his ability to testify to Detroit standards, despite not being formally questioned about them on the stand.

Another problem emerges when an expert practices in a different clinical specialty than the provider. Statutory law may control admissibility in these instances. In the second introductory case, a motorcycle accident victim was treated by a plastic surgeon but offered a dentist's testimony in the subsequent malpractice suit. The Court of Appeals of Kansas, based on a statutory provision, determined that the dentist could not testify.[7] The statute required that a plaintiff's witness "be engaged in actual practice in the same field in which the defendant is licensed."[8] Since the defendant was a licensed medical practitioner and the plaintiff's expert was a licensed dentist, the testimony had to be excluded under the plain meaning of the statute. Absent a statutory exclusion, courts may admit testimony from various sources.

A trial court in South Carolina excluded the testimony of an emergency room technician regarding proper intubation procedures.[9] The plaintiff alleged his two front teeth were chipped by the defendant anesthesiologist during intubation. The technician's testimony, excluded by the trial court, was deemed appropriate on appeal, since the requirement for admissibility in malpractice cases is for the witness to "have special expertise by way of training to compare with that of the physician who is defending the charges." After a lengthy discussion of the technician's qualifications and experience regarding intubation, the appeals court opined that the proper emphasis was on intubation procedures—an area in which the witness was qualified to testify.

Where the witness is a physician, not a medical technician, some courts will allow greater leeway in admitting the testimony. This demonstrates a recognition by the judiciary that any physician, general practitioner or specialist, has acquired knowledge and experience that the average layperson has not. Nevertheless, a determination on whether a physician's breach of duty caused the patient's injury is often substantially better facilitated by the testimony of a specialist. A recent Texas decision demonstrates the point.[10]

After being assaulted and struck on the neck, a young lady was brought to the emergency department. She was nauseated, disoriented and uncooperative. Physicians neither performed a CT scan of the head, nor consulted a neurosurgeon. Following her discharge, she developed an excruciating headache and vomiting, and a subsequent CT scan revealed a skull fracture. The patient died of her injuries.

During the trial for wrongful death brought by the girl's parents, plaintiffs offered an emergency medicine physician who testified on the standard of care generally in the emergency department and the negligence of the defendant physicians. However, his attempt to pinpoint the actual **cause** of death met with objections from the defendants. The defense argued that only a neurosurgeon "should testify that the failure to immediately perform a CT scan leading to an untreated brain injury" proximately caused the victim's death. While the trial court agreed with the defendants, the court of appeals did not, concluding that "[t]he fact that [the witness] is not a specialist in neurosurgery goes to his credibility with the jury, not the admissibility of his testimony."

In determining whether to let a physician testify in an area that is not his specialty, the courts often stress the crucial reason an expert is needed. If a potential witness has the skill, knowledge, or ability to draw

an inference that the average layperson could not draw, then that may be enough to qualify him or her to testify. Whether a specialist will be given more credence than another physician is solely for the jury to decide.

DAUBERT

The last issue to be discussed regarding expert testimony in medical malpractice litigation is, in theory, the most fundamental: Should proffered testimony be excluded because it is unsound scientifically, therefore unreliable and necessarily irrelevant to a jury determination?

For almost 70 years, many courts applied the *Frye* rule to include or exclude scientific evidence.[11] This rule derived from a criminal case heard in federal court in the District of Columbia. The court reviewed whether a primitive lie detector test using systolic blood pressure should have been admitted based on one "expert's" testimony. The court found no "general acceptance" within the scientific community regarding the theory, and the expert was consequently rejected. The court emphasized that "general acceptance" within the appropriate professional community would be the criterion courts would look to in deciding admissibility. Put another way, if the relevant scientific community had reached consensus, then the federal courts could hear the evidence.

In the following years, many commentators in the legal literature criticized the *Frye* rule. Some considered the effect of the rule as too conservative, excluding the results of novel studies—even those proven, in time, to be valid. Most importantly, many argued that the rule of evidence, derived from a single case, was actually superseded by the adoption of the Federal Rules of Evidence in 1973.

In an attempt to resolve this controversy, the U.S. Supreme Court decided *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,[12] a suit brought to recover for birth defects allegedly caused by the mother's ingestion of Bendectin during her pregnancy. At trial, the defendant pharmaceutical firm objected to the substantive use of expert testimony offered to support the plaintiff's case. The testimony would have established a link between birth defects and Bendectin, premised upon "recalculations" and re-analysis of existing scientific literature that the witnesses had never published or subjected to peer review. Employing language similar to *Frye*, the trial court excluded the evidence, a determination that was appealed to the federal circuit court. The Supreme Court agreed to review the case and then remanded it for a new trial after explicitly rejecting the applicability of "general acceptance" to scientific evidence in the federal courts.

The Supreme Court opinion does not address the value, worth, or reliability of the evidence offered. The opinion simply declared an end to the era of the *Frye* rule as an absolute determinant of admissibility. General acceptance is no longer a requisite component of admissibility. In essence, if the testimony will assist the trier of fact in understanding a relevant piece of evidence, then such testimony will be permitted from qualified experts. The court indicated, however, that "knowledge", "skill", and "experience" require a certain degree of credibility and authoritative backing. Consistent with a reading of the Federal Rules of Evidence in their entirety, the Supreme Court stated that evidence similar to that submitted in *Daubert* was to be the subject of a separate hearing by the trial court judge.

Trial judges were offered several suggestions for use in making a determination on the admissibility of technical scientific evidence. Judges should ask: 1) whether the proposed theory i s testable, or has been tested; 2) whether it has been subjected to publication and peer review; 3) what the error rate is; 4) whether the theory or technique is accepted in the scientific community; and 5) the extent to which the 'scientific method' was used. The Court emphasized that no one factor is determinative and provided judges with considerable discretion.

Questionable scientific evidence is often offered in medical malpractice or toxic tort litigation. A recent and well-publicized lawsuit in Florida demonstrates the applicability of *Daubert*.[13] A federal district court granted summary judgment to the defendant producers of cellular phones because the plaintiff was unable to offer competent testimony that his wife's brain tumor was caused or exacerbated by her use of a cellular phone. The plaintiff's expert was ready to testify that "the use of a cellular telephone is a health hazard and would likely accelerate the growth of brain

tumors in humans." However, "the expert's bold assurance of validity" was not enough to satisfy the judge, and absent expert testimony as to causation, the suit was summarily dismissed.

Much like the disparate opinions of scientific experts, different courts examining similar facts can reach different conclusions. Statutes of the controlling jurisdiction, court precedents and evidentiary rules can be determinative. The *Daubert* and *Frye* tests are both worth knowing, since *Daubert* directly controls only federal courts and a significant number of states still utilize the older test of "general acceptance" for admissibility.

CONCLUSION

Rare is the experienced clinician in the United States who has never been engaged in a medicolegal dispute. For health care providers, knowing what is required from expert testimony, who may testify as an expert in a given jurisdiction, and what testimony will be allowed into evidence is integral to understanding that sector of the legal system they most commonly frequent.

REFERENCES

1. *Sims v. Schweiker*, 651 N.E.2d 348 (Ind. 1995).
2. *Tompkins v. Bise*, 893 P.2d 262 (Kan. 1995).
3. Fed. R. Evid. 702.
4. Amtz RN. Competency of medical expert witnesses: Standards and qualifications. Creighton Law Review. 1991; 24:1359.
5. *Hall v. Hilbun*, 466 So.2d 856 (Miss. 1985).
6. *Bahr v. Harper-Grace Hospitals*, 528 N.W.2d 170 (Mich. 1995).
7. *Tompkins v. Bise*, 893 P.2d 262 (Kan. 1995).
8. KAN. STAT. ANN. § 60-3401 (1993).
9. *Gooding v. St. Francis Xavier*, 454 S.E.2d 328 (S.C. 1995)
10. *Heise v. Presbyterian Hospital of Dallas*, 888 S.W.2d 264 (Tex. Ct. App. 1994).
11. *Frye v. United States*, 293 F.1013 (D.C. App. 1923).
12. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786 (1993).
13. *Reynard v. NEC Corporation*, 887 F.Supp. 1500 (Fla. 1995).

INSTRUCTIONS TO EARN 5 CME CREDIT HOURS

Using the reply card on the inside back cover, answer all 20 questions below. Each question has only one correct answer. An answer key is provided on page 29.

- QUESTIONS -

1. The DoD Malpractice Database was established for all of the following purposes **EXCEPT** to:
   A. Assist internal DoD health care quality assurance and risk management programs.
   B. Stimulate study of high risk clinical areas by other quality management efforts, such as CEPRP.
   C. Remove the clinical privileges of health care providers who are negligent.
   D. Educate health care providers about clinical errors that have repeatedly occurred.

2. According to this database, the most frequent allegation of medical negligence within DoD is related to:
   A. surgical procedures.
   B. diagnoses.
   C. treatments.
   D. obstetrical care.

3. Regarding DoD malpractice claims:
   A. Approximately 17 percent involve pregnancy, childbirth and the puerperium.
   B. Approximately 10 percent involve the circulatory system.
   C. Over 50 percent involve cancer.
   D. All of the above.
   E. A. and B. only.

4. All of the following statements are true regarding DoD malpractice claims **EXCEPT**:
   A. The annual rate has been between four and eight claims per 100 physicians since 1986.
   B. Nearly one-fourth of the claims involve patients two years and younger.
   C. Approximately one-third are administratively denied as without merit.
   D. Nearly two-thirds of the total amount paid involved merely 10.7 percent of the paid claims.
   E. One-eighth involve orthopedic surgeons.

5. The locality rule limited:
   A. a plaintiff to file suit in only one locality.
   B. a physician to practice in only the same locality as she was trained.
   C. a plaintiff to proffer the testimony of experts only from the same locality as the defendant.
   D. a physician to defend claims in one locality.
   E. a judge to preside over cases involving only one locality.

6. Expert testimony in medical malpractice litigation is required to establish:
   A. the standard of proper professional skill or care.
   B. a breach of that standard by a defendant.
   C. a causative link between a defendant's breach and a patient's injury.
   D. all of the above.

7. The *Daubert* decision by the Supreme Court:
   A. set explicit criteria for determining the value and reliability of scientific evidence.
   B. eliminated "junk science" from the courtroom.
   C. held Bendectin responsible for birth defects.
   D. confirmed an end to the era when the *Frye* rule solely determined admissibility of scientific evidence.

8. In medical malpractice cases, a deviation from a practice guideline is:
   A. negligence *per se.*
   B. clear evidence of substandard practice.
   C. admissible and may support a rebuttable inference of substandard practice.
   D. evidence of no negligence.
   E. never admissible into evidence.

9. All of the following statements are true regarding the use of practice guidelines in medical malpractice cases **EXCEPT**:
   A. In Maine, practice guidelines may be introduced into evidence only by a defendant.
   B. Maryland prohibits plaintiffs or defendants from citing practice guidelines at trial.
   C. Washington encourages the use of practice guidelines in medical malpractice cases.
   D. Federal legislation was passed in 1995 that links adherence to practice guidelines with protection against malpractice claims.

10. An American College of Physicians survey regarding practice guidelines reported:
    A. a uniformly unfavorable reaction.
    B. an objection to guidelines on the grounds that they reduce autonomy.
    C. a consensus that guidelines would reduce medical malpractice suits.
    D. all of the above.
    E. none of the above.

CONTINUING MEDICAL EDUCATION QUIZ, cont'd

11. Neck pain:
    A. rarely occurs.
    B. often indicates a serious medical condition.
    C. rarely indicates a serious medical condition.
    D. rarely is self-limited and often dramatically worsens,if not treated.
    E. none of the above.

12. The diagnosis of a spinal epidural abscess is difficult because:
    A. a spinal epidural abscess is a common disease.
    B. providers are not taught today how to take a proper clinical history.
    C. the presenting symptoms are often unusual.
    D. a spinal epidural abscess is a relatively rare disease for which a diagnosis must be suspected and pursued by providers who may have never encountered a case clinically.
    E. all of the above.

13. Regarding traumatic neck injuries:
    A. Cervical disc disease always presents as a nagging chronic condition without a traumatic antecedent.
    B. Most neck trauma results in serious neurologic injury.
    C. Delayed diagnoses of cervical fractures are rare because every traumatized patient's cervical spine is x-rayed.
    D. The American College of Surgeons advises that a cervical spine fracture be assumed in any patient with multisystem trauma because such an injury is potentially devastating when not suspected and properly handled.
    E. A cervical spine CT is required in most cases.

14. Regarding breast cancer:
    A. Mammography has replaced histopathologic analysis for diagnosis.
    B. The disease occurs most frequently in women of childbearing age.
    C. Approximately 100,000 cases have been diagnosed in the last five years.
    D. All of the above.
    E. None of the above.

15. Medical malpractice claims involving breast cancer:
    A. are the most frequent cause, by disease category, for payment and a leader in the total amount of indemnification.
    B. may be filed against family practitioners, internists, surgeons, radiologists or pathologists.
    C. represent a new form of tort liability in this country.
    D. all of the above.
    E. A. and B. only.

16. According to the 1995 PIAA study on malpractice claims involving the diagnosis of breast cancer:
    A. Patients at presentation were relatively young.
    B. Patients usually detected the lesion themselves.
    C. Mammography was either negative or equivocal, when a lesion was present, in nearly 4 out of 5 cases.
    D. All of the above.
    E. A. and B. only.

17. Lessons learned from analyzing breast cancer malpractice claims include:
    A. Breast cancer can occur in relatively young patients, some when pregnant.
    B. The clinical presentation of breast cancer includes painful or tender breast lesions.
    C. Diagnostic mammography does not currently exist, and breast cancer can be diagnosed now only upon the satisfaction of histopathologic criteria.
    D. The potential for false negative biopsies is heightened when evaluating small breast lesions.
    E. all of the above.

18. Mechanisms of managed care include:
    A. restrictions on referrals to specialists.
    B. development of criteria for ordering diagnostic tests.
    C. limitations on performing certain procedures.
    D. all of the above.
    E. none of the above.

19. Recent court opinions indicate that, in managed care systems, a physician should make decisions primarily based upon:
    A. medical necessity and the patient's best interests.
    B. strict interpretation of cost-savings mechanisms.
    C. telephone authorization of services by an insurer.
    D. all of the above.
    E. none of the above.

20. Referrals to specialists may constitute the largest liability risk for a primary care provider in managed care because:
    A. most specialists in managed care networks are incompetent.
    B. when an incompetent specialist renders substandard care, a primary care provider may be accused of negligent referral.
    C. too many unnecessary specialty referrals are made.
    D. all of the above.
    E. none of the above.

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